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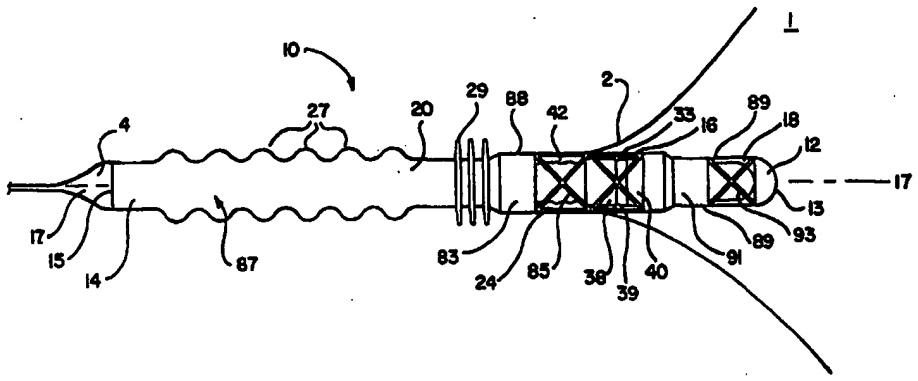


(57) Abstract

The present invention is an apparatus, and method for controlling urinary incontinence in an individual. The apparatus comprises a tubular device (10) for placement in the urethra of the individual. A proximal portion (12) of the device is adapted for placement in communication with the bladder of the individual, and a distal portion (15) of the tubular device is opposite from the proximal portion. A lumen (21) extends through the device from a distal opening (19) located in the distal portion to a proximal opening located in the proximal portion. The device includes an actuator (22) which is responsive to an actuation force or pressure applied thereto. A valve (42) is operated by the actuator which operates to open, and close the proximal opening. In one aspect, the valve is comprised of a flexible bellows which is movable between first and second positions to alternately open and close the proximal opening. According to a further aspect of the device, the actuator is damped so that its operation of the valve requires application of a sustained actuation force or pressure for a predetermined duration of time. In one embodiment, the actuation pressure results from fluid pressure within the bladder. In another embodiment, the actuation force results from application of a magnetic field.

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# URETHRAL APPARATUS WITH HIGH FLOW VALVE AND METHODS OF USE THEREOF

## REFERENCE TO RELATED APPLICATIONS

The present application claims priority to U.S. provisional application Ser. No. 60/036,944, filed February 7, 1997, the entire disclosure of which is incorporated herein by reference, and relates to U.S. application Ser. No. 08/914,487 entitled "URETHRAL DEVICE WITH ANCHORING SYSTEM" filed August 19, 1997, and U.S. application Attorney Docket No. 8886/8 entitled "URETHRAL APPARATUS WITH POSITION INDICATOR AND METHODS OF USE THEREOF" filed on even date herewith, the entire disclosures of which are incorporated by reference herein.

## FIELD OF THE INVENTION

The present invention relates generally to apparatuses for placement in the urethra and methods of using such apparatuses, and more particularly to apparatuses that can be positioned in the urethra for short-term or long-term use and that provide functions such as valving for flow control.

## BACKGROUND OF THE INVENTION

Urinary problems include urine retention, incontinence, and difficult urination. Inability to evacuate retained urine may lead to damage of the epithelium and detrusor muscles associated with the urethra and to an increased potential for bacterial invasion and urinary tract infection. Incontinence, which is the inability to retain urine because of the paralysis or relaxation of sphincter muscles or because of the contraction of longitudinal muscular layers of the bladder, is not only a social problem but also one of the leading causes of institutionalization of the elderly. Difficult urination or dysuria can lead to problems similar to those of urine retention.

Devices have been developed and used in attempts to correct the problems of urine flow. One conventional device is the indwelling Foley catheter. The Foley catheter has an inflatable balloon attached at one end. The Foley catheter is positioned in the urethra with the proximal end in the bladder. The inflatable balloon is used to

anchor the proximal end of the Foley catheter in the bladder. Urine enters the Foley catheter through drainage holes which are located along the catheter shaft proximal of the balloon. The distal end of the Foley catheter extends externally of the urethra and is attached to a urine collection system. The need for an external urine collection system makes the Foley catheter undesirable to many individuals. Furthermore, because the balloon occupies a position in the bladder adjacent to the drainage openings, it is difficult to evacuate the bladder completely, which may be uncomfortable and may possibly lead to infections.

Another approach to address problems of urine control is intermittent self-catheterization. According to this conventional approach, the patient inserts a urinary drainage catheter to evacuate the bladder on a regular basis as needed. This procedure is time-consuming and can lead to infection. Further, it can also lead to a real or perceived lower quality of life. If done in public restrooms, self-catheterization can be embarrassing and can lead to an increased risk of infection.

Another approach that has been taken to address urinary control problems is to implant collagen and other materials alongside the urethra in an attempt to narrow the urethral passageway. These materials have been known to migrate and lose their effectiveness. Still other approaches involve surgeries, such as bladder neck suspensions, sling operations, and implanted artificial urinary sphincters. Still other approaches include occlusive devices that must be removed to void, while other devices are valved devices.

Valved intraurethral devices have been developed for use by individuals who have difficulties controlling urine flow. There are several factors that may have limited more widespread usage of valved intraurethral devices. One factor is that the parts of an intraurethral device which are in the flow path of the urine should be able to withstand exposure to the urine. Over time, components which are exposed to urine may become encrustated with solids from the urine. Another factor that may have limited more widespread use of valved intraurethral devices has been the inability of such devices to void the bladder completely and possess sufficient urine flow rates.

Accordingly, there is a need for an indwelling urethral device that can be used by individuals to effect the voluntary control of urine.

## SUMMARY OF THE INVENTION

To address the above concerns, the present invention provides an apparatus and method for controlling urinary incontinence in an individual. The apparatus comprises a tubular device for placement in the urethra of the individual. A proximal portion of the device is adapted for placement in communication with the bladder of the individual and a distal portion of the tubular device is opposite from the proximal portion. A lumen extends through the device from a distal opening located in the distal portion to a proximal opening located in the proximal portion. The device includes an actuator which is responsive to an actuation force or pressure applied thereto. A valve is operated by the actuator and operates to open and close the proximal opening. In one aspect, the valve is comprised of a flexible bellows which is movable between first and second positions to alternately open and close the proximal opening. According to a further aspect of the device, the actuator is damped so that its operation of the valve requires application of a sustained actuation force or pressure for a predetermined duration of time. In one embodiment, the actuation pressure results from fluid pressure within the bladder. In another embodiment, the actuation force results from application of a magnetic field.

## BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an expanded elevational view of a present embodiment of an indwelling urethral device positioned within the bladder and urethra.

Figure 2 shows a partial sectional view of the embodiment of Figure 1.

Figure 3 is an expanded elevational view of the urethral device of Figure 1 positioned within the bladder and urethra shown in another stage of operation.

Figure 4a is an expanded distal end view of the actuator rod of Figure 2.

Figure 4b is an expanded side view of the actuator rod of Figure 2.

Figure 4c is a expanded proximal end view of the actuator rod of Figure 2.

Figure 5 is an expanded elevational view of another alternate embodiment of an indwelling urethral device.

Figure 6 shows an expanded elevational view of another embodiment of an

indwelling urethral device positioned within the bladder and extending into the bladder neck and urethra.

Figure 7 shows a partial sectional view of the urethral device of Figure 6.

Figure 8 shows a further expanded view of the proximal portion of the urethral device of Figures 6 and 7.

Figure 9 shows an expanded partial sectional view of the urethral device of Figures 6, 7, and 8 and an external magnet causing the urethral device to be the in another stage of operation.

Figure 10 shows a side view of a third embodiment of an indwelling urethral device.

Figure 11 is a sectional view of the proximal portion of the embodiment of Figure 10.

Figure 12 is a sectional view of the proximal portion of a fourth embodiment of an indwelling urethral device.

## DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

### I. FIRST EMBODIMENT

The first embodiment includes a urethral device and associated method of use that provide for the voluntary control of urine removal from the bladder of an individual who suffers from urinary incontinence or other urine-control problems. The individual may be either a male or female human, or alternatively, embodiments of the device may be used in other mammals or even other non-mammal animals with suitable changes in dimensions.

The urethral device of the first embodiment is hydraulically activated. The device includes a pressure-sensitive actuator which is operated by voluntary application of pressure to the bladder region. The pressure can be either externally applied (e.g. pressing the abdomen in the region of the bladder with the fingers) or internally applied (e.g. contracting the muscles in the region of the bladder as one would do during normal urination). In a preferred embodiment, the actuator requires the sustained application of pressure to the region of the bladder for a suitably long duration of time to open a valve to discharge urine from the bladder through the device. This provides

for the damping of pressure impulses which might occur due to laughing, coughing, exercising, and so on.

Further in a preferred embodiment, the actuating components are located outside the flow path through the device by which urine is evacuated from the bladder. This feature enables the dimensions of the flow path to be maximized to provide the greatest flow rate and to facilitate complete voiding of the bladder.

Figures 1-5 show a first embodiment of an indwelling urethral device 10. In Figure 1, the urethral device 10 is shown positioned partially within a bladder 1 of an individual. The urethral device 10 extends distally into a bladder neck 2 and urethra 4 of the individual. The urethral device 10 has a body 20 with a proximal portion 12 terminating at a proximal end 13 and with a distal portion 14 terminating at a distal end 15. The body 20 has a wall 22 with an exterior surface 24 and has a generally tubular shape around an axis 17. The cross-sectional shape of the body 20 may be generally round or may be flattened to conform to the anatomical shape of the urethra of the individual in whom the device is positioned.

The body 20 includes a main portion 87, a first casing 88, and a second (or proximal) casing 89. The second casing 89 forms part of the proximal portion 12 of the body 20 and extends distally to the first casing 88. The main portion 87 is formed of a tubular member and comprises all or part of the distal portion 14 of the body 20. The main portion 87 extends from the distal end 15 proximally to the distal end of the first casing 88. The proximal end of the main portion 87 joins the distal end of the first casing 88. The proximal end of the first casing 88 joins the distal end of the second casing 89.

The main portion 87 includes a distal opening 19 which communicates with a lumen 21 which extends from the distal opening 19 through the main portion 87. The distal opening 19 may be provided with a recess 23 or other coupling arrangement 92 which can be used with other equipment in order to position and remove the urethral device 10. The exterior surface of the main portion 87 may include anchors 27 or other means for securing the urethral device 10 in the urethra once is has been positioned. The anchors 27 may also facilitate positioning the urethral device in the urethra. One or more sealing rings 29 may also be located on the exterior surface of

the main portion 87. The sealing rings 29 may be located along a proximal part of the main portion 87 adjacent to the first casing 88. The sealing rings 29 are used to form a fluid barrier between the urethral device 10 and the urethra 4 to limit or reduce leakage of urine around the outside of the urethral device.

In one embodiment the main portion 87 of the device 10 is produced using a composite construction of a base tube and cast external features. A base tube is constructed as a braid reinforced silicone tube using a stainless steel wire braid and Shore A 60 durometer silicone compound as the tube polymer (tubing produced by New England Electric Wire Corp. Lisbon, NH). The internal diameter of the base tube is 0.160 inches using a braid core diameter of 0.180 inches. The external diameter of the base tube is 0.210 inches.

The urethral apparatus 10 has an overall length such that it resides entirely within the urinary tract of the patient, preferably primarily within the urethra, except to the extent to which the proximal end 13 extends partially or completely into either the bladder or the bladder neck. The distal end 15 of the device 10 does not extend outside the urethra after it is positioned. In present embodiments, the device is less than 10 cm in length in versions for adult-sized male users and 5 cm in length for adult-sized female users, but more preferably less than 5 cm in length for female users.

The device 10 may be sized from about 10 French to 34 French to accommodate the large range of urethral sizes from infants to adults. The exterior surface of the device is constructed of molded silicone or alternatively of latex. Alternative materials include molded polyurethane, polyethylene, polycarbonate, or other biocompatible materials.

The first casing 88 includes one or more drainage ports 16 formed by one or more openings that extend through the wall 83 from which the first casing 88 is made. The drainage ports 16 allow fluid to pass from outside the first casing 88 to the interior thereof. In a present embodiment, the drainage ports 16 are formed by relatively large spaces formed between skeletal structural parts or struts 85 which form part of the wall 83 of the first casing 88. This construction provides a relatively large passageway for fluid flow across the casing wall boundary thereby posing only limited resistance to flow.

The second casing 89 includes one or more actuator ports 18. Like the drainage ports 16 in the first casing 88, the actuator ports 18 may be formed by openings that extend through the wall 91 from which the second casing 89 is formed. The actuator ports 18 allow fluid (or at least fluid pressure) to pass from outside the second casing 89 to the interior thereof. Like the drainage ports 16, the actuator ports 18 may be formed by relatively large spaces formed between skeletal structural parts or struts 93 which form part of the wall 91 of the second casing 89. This construction provides a relatively large passageway for fluid flow across the wall boundary of the second casing 89 thereby posing only limited resistance to flow.

Referring to Figures 1 and 2, located inside of the first casing 88 is a valve which in a preferred embodiment is a bellows valve 42. The bellows valve 42 is formed of a flexible, resilient, and fluid-impervious tubular material. The bellows valve 42 defines a urine-flow passageway 43 through the interior thereof. A distal end of the bellows valve 42 is coupled to a mounting flange 80. The mounting flange 80 is coupled to a proximal end of the tubing 84 which forms the main portion 87. The tubing 84 in turn is coupled to a distal end of the interior wall of the first casing 88. The connections between the distal end of the bellows valve 42, the mounting flange 80, the tubing 84, and the first casing 88 may be made by any suitable means of connection, such as adhesives 94, ultrasonic bonding, welding, multi-part epoxies, friction fitting, shrink fitting, or other connection methods.

At least one marker used for device location using ultrasound or x-ray can be located along the length of the urethral device 10. In a present embodiment, a marker 90 is located between the mounting flange 80 and the tubing 84.

Located at a proximal end of the bellows valve 42 is an ultrasoft annular ring 38. The annular ring 38 has a soft flexible proximal rim or lip 33. The annular ring 38 defines a proximal opening 39 (shown in Figure 3) that leads to the urine-flow passageway 43 in the bellows valve 42. The proximal opening 39 defined by the annular ring 38 provides the entrance into the urethral device 10 by which urine can be eliminated from the bladder 1.

Coupled to an inside wall of the ultrasoft ring 38 is a distal end of an actuator rod 72. As shown in Figures 4a, 4b, and 4c, the actuator rod 72 is formed of a central

shaft portion 73 having a distal end coupled to a distal ring 78 by means of radial struts 75. The actuator rod 72 also includes a disk 77 coupled to a proximal end of the central shaft portion 73. The actuator rod 72 may be formed of a one piece metallic or plastic material.

Located inside the first casing 88 directly adjacent proximally from the proximal end of the ultrasoft ring 38 is a generally cylindrically shaped plug 41. A proximal end of the plug 41 is fixed to the inside wall of the first casing 88. The central shaft portion 73 of the actuator rod 72 extends through an axial bore 47 located through the plug 41. The exterior distal shape of the plug 41 is slightly tapered so that an outer diameter of the plug 41 is less at its distal end than at its proximal end. The exterior of the plug 41 may be tapered along its entire length (e.g., frusto-conical) or alternatively, the taper may begin at an intermediate location along the length of the plug.

The tapered, distally facing exterior surface of the plug 41 forms an angular flange 40. The angular flange 40 forms a proximal valve seat against which the ultrasoft ring 38 moves to form a seal to prevent fluid from entering into the proximal opening 39 defined by the ultrasoft ring 38.

The bellows valve 42, and in particular the proximal end of the bellows valve 42, is displaceable along the axis 17. The bellows valve 42 may be formed of a spring 44 encapsulated by a very thin plastic sleeve or layer 45. The layer 45 may be composed of a suitably strong, yet flexible material, such as PTFE. The encapsulated spring 44 provides the bellows valve 42 with a shape-memory property. Thus, the bellows valve 42 can be deformed in length (i.e. shortened or stretched) by application of a compressive or tensile force, and the bellows valve 42 will resume its original size upon removal of the applied force. In alternative embodiments, the bellows spring 44 can be omitted and instead the bellows material can be selected to provide the desired shape-memory property.

Referring to Figure 2, inside the second casing 89 are a sealed proximal fluid reservoir 60 and a sealed distal fluid reservoir 62. The proximal and distal fluid reservoirs 60 and 62 are filled with a fluid 58. The proximal and distal fluid reservoirs 60 and 62 are separated from each other by a barrier plate 64. Located in the barrier

plate 64 is a fluid passageway 66. The fluid passageway 66 provides a restricted fluid path between the proximal and distal reservoirs 60 and 62 by which the fluid 58 can pass between the reservoirs.

Part or all of the wall which forms the proximal reservoir 60 is formed of a flexible material which forms a proximal membrane 52. The proximal membrane 52 is located inside the second (proximal) casing 89 adjacent to the actuator ports 18. Thus, the proximal membrane 52 is exposed to fluid or fluid pressure from the area outside of the second casing 89.

Located inside the proximal reservoir 60 is a proximal spring 56. The proximal spring 56 is located axially inside the proximal reservoir 60. The proximal spring 56 has a preset load of approximately .7 gram. A distal end of the proximal spring 56 bears against the proximal side 67 of the barrier plate 64. Specifically, the distal end of the proximal spring 56 is seated in a recess 63 in the proximal side 67 of the barrier plate 64. (The proximal spring is included in this embodiment although in alternative embodiments, the proximal spring may be omitted). A proximal opening 69 located at the bottom of the recess 63 leads to the fluid passageway 66 that communicates between the proximal and distal reservoirs 60 and 62.

A proximal end of the proximal spring 56 is coupled to a domed retainer 54. The domed retainer 54 is formed of a rigid material. The domed retainer 54 is located in a proximal end of the proximal reservoir 60. When the walls of the proximal reservoir 60 are formed of a flexible material, the exterior shape of the proximal end of the proximal reservoir 60 is defined by the shape of the domed retainer 54. The proximal end of the proximal reservoir 60 is adjacent to, but preferably spaced from, an inside wall of the proximal end 13 of the device defined by the proximal end of the second casing 89. The proximal end of the second casing 89 may have a shape that conforms generally to the shape of the domed retainer 54.

Part or all of the wall which forms the distal reservoir 62 is formed of a flexible material which forms a distal membrane 68. The distal membrane 68 is located inside the second casing 89 at a distal end thereof adjacent to the disk 77 of the actuator rod 72. When the distal membrane 68 is in position adjacent to the disk 77, it may be in direct contact with the disk 77, however, preferably, the distal membrane 68 is spaced

from the disk 77 by a small distance. In one embodiment, the distal membrane 68 is formed with a concave shape so that a central, on-axis portion of the distal membrane 68 is spaced away from the disk 77, as shown in Figure 2.

*Operation.* The urethral device 10 is positioned in the urethra 4. Positioning may be accomplished using conventional techniques. Alternatively, the urethral device may be positioned in the urethra using the techniques and/or equipment disclosed in the referenced copending application entitled "URETHRAL APPARATUS WITH POSITION INDICATOR AND METHODS OF USE THEREOF."

After the urethral device 10 is successfully positioned in the urethra 4 of the individual, it is used to control urine flow from the bladder 1. When the urethral device 10 is in place and the pressure of the urine in the bladder is below a predetermined threshold for a predetermined period of time, urine is prevented from entering into the urethral device 10 by the seal formed by the annular ring 38 against the angular flange 40. Under these conditions, the proximal spring 56 biases the domed retainer 54 in a proximal direction away from the barrier wall 64 causing the domed retainer 54 to be moved to a proximal position, as shown in Figure 2. When the domed retainer 54 is in its proximal position, the volume of the proximal reservoir 60 is maximized, and likewise the volume of fluid 58 filling the proximal reservoir 60 is maximized. When the volume of fluid in the proximal reservoir 60 is maximized, the amount of fluid 58 in the distal reservoir 62 is correspondingly minimized. When the fluid 58 in the distal reservoir 62 is minimized, it is insufficient to cause the distal membrane 68 to push the disk 77 of the actuator rod 72 in a distal direction. Instead, the distal membrane 68 is drawn to a proximal position, which may be everted as shown in Figure 2.

When the distal membrane 68 is in its proximal position, the distal ring 78 which is fixed to the actuator rod 72 is pushed to its proximal position, as shown in Figures 1 and 2, by the relatively low biasing force of the bellows valve 42. When the actuator rod 72 is in its proximal position, the proximal lip 33 of the ultrasoft annular ring 38, which is located at the proximal end of the bellows valve 42, is caused to bear against the angular flange 40 with a predetermined axial force. When the proximal lip

33 is located at the angular flange 40, a compressive normal force is applied to the proximal lip 33 of the annular ring 38 by the pressure of any urine in the bladder. This compressive force of the urine on the proximal lip 33, combined with the proximally directly axial force of the bellows valve 42, causes a fluid-tight seal to be formed between the annular ring 38 and the angular flange 40.

When the urethral device is in position, the fluid seal provided by the annular ring 38 and the angular flange 40 is maintained even if the fluid pressure in the bladder rises sharply for brief, transient periods of time, such as when the individual is coughing, sneezing, laughing, exercising, and so on. Because the passageway 66 between the proximal and distal reservoirs 60 and 62 is relatively narrow, short transient peaks of pressure in the bladder do not cause appreciable fluid to flow from the proximal reservoir 60 to the distal reservoir 62, therefore the seal between the annular ring 38 and the angular flange 40 remains intact.

Activation of the urethral device 10 to permit urine flow from the bladder occurs when the proximal membrane 52 and the domed retainer 54 are displaced distally along the axis 17. As mentioned above, the proximal spring 56 has a preset load of approximately .7 gram. This biasing force resists distal movement of the domed retainer 54 until bladder pressure reaches a predetermined level. The build up of pressure in the bladder to the level necessary to cause distal movement of the domed retainer 54 and proximal spring 56 may be brought about by voluntary muscular contraction. This build up may be augmented by the manual application of pressure from external of the body in the region adjacent to the bladder. To initiate movement of the domed retainer 54, the application of pressure is required to be maintained for a sustained duration of time which assures that the application of pressure is voluntary and not due to transient occurrences, such as coughing, laughing, etc.

When the bladder pressure reaches the preset magnitude for the sustained period of time, the domed retainer 54 begins to move distally. This movement is caused by the pressure build-up in the bladder which is transmitted to the outside surface (i.e. the proximal membrane 52) of the proximal reservoir 60 via the actuation ports 18. This movement of the domed retainer 54 results in fluid 58 being displaced from the proximal reservoir 60 to the distal reservoir 62 through the passageway 66

located through the barrier plate 64. As fluid 58 enters the distal reservoir 62, the distal membrane 68 is displaced distally along the axis 17 and pushes against the proximal surface 74 of the disk 77 of the actuator rod 72. In an embodiment in which the distal membrane 68 has a concave shape when the fluid 58 in the distal reservoir 62 is minimized, the distal membrane 68 may evert to form a convex, or bowed out, shape as the fluid 58 fills into the distal reservoir 62. In one embodiment, the actuator rod 72 does not move immediately when fluid 58 begins to be displaced from the proximal reservoir 60 through the passageway 66 to the distal reservoir 62. Instead, the actuator rod 72 begins moving distally when sufficient pressure is applied against the proximal surface 74 of the disk 77 of the actuator rod 72 by the distal membrane 68.

As fluid 58 continues to fill the distal reservoir 62, the distal membrane 68 continues to move distally, bearing against the proximal surface 74 of the disk 77 of the actuator rod 72 and causing the actuator rod 72 to move distally along the axis 17. Because the distal ring 78 of the actuator rod 72 is fixed to the annular ring 38, distal axial movement of the actuator rod 72 causes the annular ring 38 to likewise move distally. Distal movement of the annular ring 38 is opposed by the relatively low, proximally directed biasing force of the bellows valve 42 which is overcome by the greater, distally directed force. Thus, the bellows valve 42 is caused to be compressed. This distal movement of the annular ring 38 separates the annular ring 38 and the angular flange 40, as shown in Figure 3. This permits urine to flow into the first casing 88 through the drainage ports 16, through the proximal opening 39 in the annular ring 38, and into the passageway 43 of the bellows valve 42. Urine flows past the struts 75 of the distal ring 78 of the actuator rod 72 into the main body lumen 21 in the main body portion 87. The urine then flows out through the opening 19 at the distal end 15 of the device 10 into the urethra 4, and out from the body of the individual.

When the bladder is substantially empty, the pressure in the bladder is reduced, and urine flow ceases. The reduction of pressure in the bladder may be accomplished by voluntary cessation of the muscular contractions which caused the pressure, the removal of external application of pressure to the bladder region, by the emptying of the bladder, or a combination of these factors. This reduced pressure in the bladder is insufficient to overcome the biasing of the proximal spring 54 which moves the domed

retainer 54 back to its proximal position. This draws the fluid 58 from the distal reservoir 62 back to the proximal reservoir 60. Without the opposing force from the distal membrane 68, transmitted through the actuator rod 72, the compressed bellows valve 42 relaxes back to its extended condition, thereby sealing the annular ring 38 to the angular flange 40. At the same time, the proximal movement of the annular ring 38 causes the attached actuator rod 72 to move proximally. The urethral device is ready to prevent urine flow from the bladder again.

The operation of the urethral device 10 to permit urine flow from the bladder is controlled by the variables of time and pressure within the bladder 1. The size of the passageway 66 restricts the flow rate of the fluid 58 between the proximal reservoir 60 and the distal reservoir 62. This restriction provides a time delay between reaching the preset pressure level (at which initiation of movement of fluid from the proximal to the distal reservoirs begins) and the initiation of the movement of the actuator rod 72. In this manner, the urethral device 10 damps any involuntary pressure impulses which might occur which might open the device. A sustained pressure over a relatively substantial duration of time is required to cause a sufficient quantity of fluid 58 to move from the proximal reservoir 60 to distal reservoir 62 and, thus, to move the actuator rod 72 distally. This sequence of functions provides for predictable, controlled activation, damping, and over-pressure protection for the bladder and kidneys.

*Materials and construction:* The tubing 84 of the main body portion 87 of the urethral device is formed of a silicone tubing reinforced with a stainless steel wire-braid. The tubing has an outside diameter of approximately 5.3 mm (.210 inches) and an inside diameter of approximately 4.1 mm (.160 inches). The length of the tubing is selected and/or varied to conform to the anatomical features of the individual in whom the device is positioned. For example, the overall length can vary from less than 10 cm for male users to less than 5 cm for female users, although lengths greater than these may be provided.

In one embodiment, the silicone material of the tubing is a blend of NuSil MED 4115 and MED 4116 in a 1:1 mix ratio to achieve a Shore A 60 durometer hardness.

The stainless steel wire braid is 316L wire braided at 14 picks per inch, 2 ends per carrier, and 16 carriers using a braid core diameter of approximately 4.6 mm (.180 inches). The exterior features, such as the anchors 27 used to anchor the device in the urethra and the sealing rings 29, are formed by casting silicone rubber features onto the tubing. These features are formed from NuSil compound number MED4-4220, parts A and B blended to yield at Shore A 30 durometer feature. In one embodiment the anchoring and sealing features are formed in accordance with the above-referenced U.S. patent application Ser. No. 08/914,487.

The first casing 88 is a tubular section formed from a high durometer urethane or semi-rigid medical grade PVC. The inside diameter is approximately 6.1 mm (.240 inches), and the outside diameter is approximately 6.6 mm (.260 inches). The first casing encloses the bellows valve 42 and connects the distal end of the second casing 89 to the body tubing 84 while keeping these components coaxially aligned. The first casing maintains its cylindrical cross-section during bending.

The second casing 89 is a closed end, tubular section formed from a high durometer urethane or semi-rigid medical grade PVC. The inside diameter is approximately 5.1 mm (.200 inches), and the outside diameter is approximately 5.6 mm (.220 inches). The second casing protects the proximal and distal membranes from damage and maintains a cylindrical cross-section during bending.

In one embodiment, the annular ring 38 is constructed from Shore A 30 durometer medical grade silicone rubber (i.e. NuSil MED4-4220). The annular ring 38 has an overall length of approximately .150 inches. The annular ring 38 includes a soft flexible lip 33 which seals to the angular flange 40 to prevent urine flow into the device. The proximal lip 33 of the annular ring 38 is formed to be approximately .010 inches thick by approximately .100 inches long. In an alternative embodiment, the annular ring may be tapered.

The plug 41 is composed of Teflon TFE and Acetal (Delrin AF) blend. The present geometry of the plug is tubular with a 15-degree distal taper to form the angular flange 40. The taper allows for a slight stretching of the annular ring 38 as the ring 38 and flange 40 are pushed together by the bellows valve 42. The plug 41 is tubular to allow the actuator rod 72 to pass through the bore 47 located therein. The

proximal portion of the plug 41 is cylindrical to interface with the second casing 89. The outer diameter of the plug 41 is approximately 5.1 mm (.20 inches), and the diameter of the bore 47 is approximately 1.7 mm (.065 inches).

The flexible bellows valve 42 is constructed from a compression spring 44 within a layer formed of a thin polypropylene sleeve 45. In one embodiment, the bellows spring 44 is formed from 302 stainless steel wire. The spring constant of the bellows spring 44 is approximately 4.5 N/m (.026 lbf/in) using an approximately .15 mm (.006 inches) wire wound with 6 active coils and 2 dead coils. The sleeve or layer 45 is formed using a polypropylene film approximately .013 mm (.0005 inches) thick. The layer or layer 45 is formed using a Teflon film approximately .001 inches thick.

In alternative embodiments, the bellows valve can take other forms. For example, instead of a bellows-like construction, the bellows valve can be formed of two or more telescoping rigid sections. Like the bellows valve, the overall length of the telescoping sections could be shortened to expose the opening to the device passageway by applying a compressive axial force, as in the bellows-valve embodiment. The telescoping sections would be provided with a shape-memory property such that they would assume their original overall length after the compressive axial force was removed. As in the first embodiment, the shape-memory property could be provided by a spring located inside the telescoping sections. In still further embodiments, the valve can take forms other than a bellows or telescopic construction. For example, the valve may be gate valve or a bulb valve, or other type of valve. In such alternative embodiments of the valve, it is preferable that the actuation threshold of the valve be relatively low so that it can be operated with forces of the magnitudes indicated above.

In a present embodiment, part or all of the walls which form the proximal and distal fluid reservoirs 60 and 62, including the proximal and distal membranes 52 and 68, are formed of a single bag of extruded plastic material. In this embodiment, the bag is formed by a slow extrusion process whereby a thin film is stretched over a Teflon mandrel. The film is a polypropylene film, approximately .015 mm (.0006 inches) thick from Hytech Film Inc., Kaukauna, WI. After the extrusion process is completed, the membrane wall is approximately .0075 mm (.0003 inches)

thick. After filling with fluid 58, the proximal end of the proximal membrane 52 is sealed. The sealing is accomplished by tying the membrane bag shut and filling the tied area with a thin, cyanoacrylate-family adhesive (e.g., Sicomet™ 77). In alternative embodiments, the proximal and distal membranes may be formed of separate bags or materials.

In a present embodiment, the domed retainer 54 is composed of a medical grade polycarbonate or a high durometer urethane. This component acts on the proximal membrane 52 to return the membrane to its original shape after the bladder pressure has returned to its low pressure state (<10 cm of water pressure). The diameter of the domed retainer is approximately 4.3 mm (.170 inches).

The proximal spring 56 may be composed of a compression spring formed from 302 stainless steel wire. Its spring constant is approximately 19.25 N/m (.11 lbf/in) using approximately .15 mm (.006 inches) wire wound with 3 active coils and 2 dead coils. The proximal spring 56 is installed within the reservoir 60 formed by the proximal membrane 52. The proximal membrane is sealed so that the spring is preloaded to approximately .73 grams of force. The geometry of the spring can be varied to provide different spring constants that result in the domed retainer 54 moving at different pressure thresholds.

As mentioned above, the proximal spring may be omitted in alternative embodiments. Among some patient populations, it may not be necessary to provide the biasing force of the proximal spring and the device may be restored to a closed position using the biasing force of the bellows spring alone.

The fluid 58 performs the function of transferring the pressure acting on the surface of the proximal membrane 52 to the surface of the distal membrane 68. The fluid 58 is essentially incompressible. The fluid moves through the fluid passageway 66 in the barrier wall 64 to fill the distal reservoir 62. The diameter, length, entrance angle and roughness of the fluid passageway 66 control the rate of fluid flow. The viscosity of the fluid 58 also affects the flow rate. In a present embodiment, clean water is used as the fluid 58. In alternate embodiments, the fluid may be composed of bio-compatible oils, for example, with viscosities higher than water, to achieve a reduction in flow rate through the passageway 66.

The barrier plate 64 is made from 304 stainless steel and the passageway 66 has a diameter of approximately .3 mm (.013 inches). This diameter is sized to provide the desired amount of fluid volume through the orifice over a time period of approximately 3 seconds. The range of orifice sizes can vary greatly to allow for various time damping effects to the distal portions of the device. In one embodiment, the barrier plate 64 is formed of an injection-molded plastic part with the passageway hole 66 formed using a secondary operation to ensure an accurate hole diameter size and burr-free construction. The fluid passageway geometry and dimensions, such as the angle of entry into the passageway 66, the diameter, and the length, and any manufacturing defects such as burrs, affect the performance characteristics of the passageway. These aspects can be modified to tune the passageway performance to desired specifications. The outside perimeter surface of the barrier plate 64 is relieved to facilitate forming a seal with the extruded bag used to form the proximal and distal reservoirs.

In an alternative embodiment, a two-piece construction may be used for the barrier plate 64. In a two-piece construction, a relatively hard material, whose dimensions can be precisely controlled, is used to form the fluid passageway 66, and another, softer material is used for the rest of the barrier plate 64. For example, a stainless steel tube can be used to provide the fluid passageway 66, and an outer ring of silicone rubber can be cast over the stainless steel tube to form the rest of the barrier plate 64. A two-piece embodiment of the barrier plate 64 provides the advantage that the outside portion can be formed of a more flexible material to facilitate placement and use of the device.

The actuator rod 72 and the proximal disk 77 are formed from a 304 stainless steel wire and disk, respectively. The diameter of the wire is approximately .51 mm (.020 inches) and the thickness of the disk is approximately .51 mm (.020 inches).

The mounting flange 80 is formed of a short tubular section of medical grade polycarbonate. In one embodiment, the mounting flange has an outside diameter of approximately 3.9 mm (.154 inches) and an inside diameter of approximately 3.4 mm (.134 inches).

The marker 90 is formed from a relatively radiopaque or acoustically opaque

material, such as a metal wire coil. In one embodiment the marker 90 is formed using 304 stainless steel wire having a diameter of approximately .13 mm (.005 inches ) at a pitch of approximately .18 mm (.007 inches).

The coupling insert 92 at the distal end of the device is formed of a short tubular section with an internal relief along its axis. The coupling insert 92 is made of medical grade polycarbonate. The present dimensions of the coupling insert 92 are approximately 3.9 mm (.154 inches) outside diameter and approximately 3.6 mm (.140 inches) inside diameter. The coupling insert 92 may be used in cooperation with an insertion tool as disclosed in the above referenced copending U.S. patent application Attorney Docket No. 8886/8 entitled "URETHRAL APPARATUS WITH POSITION INDICATOR AND METHODS OF USE THEREOF" filed on even date herewith.

For most bonding connections, a silicone-based adhesive, such as NuSil MED-1011 (acetoxy cure system) or NuSil LSR1-9879, are used with CF1-135 primer to speed bonding. Medical grade, two-part epoxy such as Tra-Con P/N Tra-Bond FDA-8 may be used also.

*Advantages:* The embodiments of the urethral device described above include several advantages. One of the advantages is that the device is able to provide a fluid seal with a relatively very low force, for example less than approximately 8 grams. This enables the device to use very low pressures in the bladder to accomplish fluid sealing. This feature is provided by one or more of the following factors: the ability of annular ring 38 to stretch and conform to the shape of the angular flange 40, the proximal profile of the annular ring 38 that is exposed to urine pressure, and the shape and material characteristics of angular flange 40.

The ability of the annular ring 38 to stretch and conform is a function of both its material and design. In one embodiment, the annular ring 38 is constructed of soft silicone rubber that allows the annular ring to stretch easily. The wall thickness and length of the annular ring 38 also influence its stiffness and/or its ability to stretch. The wall thickness of the annular ring directly influences the stiffness of the ring, and the length of ring inversely influences its stiffness. For example, an annular ring with a

wall thickness of .010 inches and a ring length of .100 inches requires a 2-gram axial force to seal to an angular flange with a 15-degree taper. By appropriate modification of the parameters of wall thickness and length, the ability of the annular ring to stretch, and similarly the amount of force required to seal annular ring 38 to the angular flange 40, can be changed.

The lip seal arrangement is advantageous because it uses external pressure (in this case urine pressure from the bladder) to assist in sealing the proximal lip 33 of the annular ring 38 to the angular flange 40. The annular ring 38 is pressed to the angular flange 40 by the urine pressure acting on the outer circumference of the proximal lip 33 of the annular ring 38.

In a present embodiment, the proximally facing, projected surface area of the annular ring 38 is minimized. Since the outside surface of the annular ring 38 is exposed to the fluid pressure within the bladder, the proximally facing projected surface area of the proximal lip of the annular ring 38 experiences a distally directed force generated by this bladder pressure. The magnitude of this distally directed force is equal to the projected proximally facing area of the proximal lip times the urine pressure. This distally directed force acts against the sealing force. For this reason the proximally projected surface area of the annular ring is minimized.

The shape, cylindrical taper, and material characteristics of the angular flange 40 assist in minimizing the amount of sealing or axial force applied to the annular ring 38. The taper angle increases the normal force (or stretch force) component of the axial force applied to the annular ring 40. This increase in normal force increases the amount of friction between the annular ring 38 and the angular flange 40. The use of a low-friction material for the angular flange 40 reduces the amount of friction between the annular ring 38 and the angular flange 40. The reduction in friction force allows a greater portion of the axial force to be used to stretch the annular ring 38.

Sealing an annular ring of the size disclosed above to an angular flange with a 15-degree taper requires approximately 1 to 2 grams of axial force to form a fluid-tight seal at approximately 70 cm of water pressure. The ability to achieve a fluid-tight seal at this magnitude of axial force is advantageous. It enables the pressure within the bladder (transformed into an axial force) to open the annular ring to allow voiding the

bladder when a preset pressure level is attained. The seal is further capable of sealing at pressures from approximately 0 cm to approximately 150 cm of $H_20$ which the bladder can generate.

The length of the angular flange 40 also influences the performance of the device. During initial distal movement of the annular ring 38, the angular flange 40 is in the urine flow. The length of the angular flange 40 influences how much travel is required by the annular ring 38 to clear the angular flange in order to achieve the desired flow rate. A short angular flange 40 improves device performance with regard to flow rate and magnitude of the annular ring displacement.

The ability of the bladder to produce sufficient pressure to initiate the drainage of urine is limited to voluntary control by the individual due to normal micturition urges, contractions, or external Crede methods. This pressure, which is externally applied to the bladder, is transformed into a force that can be used to place the device in an open condition by the separation of the annular ring 38 from the angular flange 40. For example, if the force on the domed retainer 54, which has a diameter of approximately .180 inch, were to transform a bladder pressure of 50 cm of water pressure completely to force, the device would generate 8.2 grams of force. Thus, 8.2 grams of force would be the maximum amount of force available to open the system. This is a relatively small amount of force. With a device according to the first embodiment, the device closes and, conversely, opens at forces of less than approximately 10 grams and preferably at forces less than approximately 5 grams.

Another advantageous feature of the disclosed embodiment is the use of the flexible bellows valve. The flexible bellows valve allows the proximal end of the annular ring 38 to be displaceable along the axis 17 without incurring substantial frictional losses inherent to other movable sealing methods (i.e., shaft seals).

Still another advantage of the disclosed embodiment is that the flow-control actuator components (e.g., the fluid barrier plate and spring) are not in the exit flow path of urine (via the drainage ports 16 in the first casing). This provides several advantages. First, encrustation on the actuation components is reduced since these critical components are not in the urine flow path. In addition, since these components are outside the flow path, the size of the flow path can be increased, thereby permitting

a high flow rate of urine through the device.

The passageway 66 through the barrier plate 64 is constructed to have different flow characteristics depending on whether fluid is flowing proximally or distally. The proximal (or closing) movement of the annular ring 38 does not occur until the actuator rod 72 is first allowed to move proximally. This proximal movement of the actuator rod 72 is restricted and subjected to the time and pressure delay characteristics provided by the proximal and distal reservoirs 60 and 62. This delay permits full voiding of the bladder prior to resealing of the annular ring 38 with the angular flange 40 to close the entrance to the fluid-flow passageway 43.

Another advantage of the disclosed device is that it is insensitive to relatively short high pressure conditions in the bladder. Activities such as coughing, sneezing, exercise, and laughing can cause peak pressures as great as 150 cm of $H_20$. However, these peak pressures only last for about one second. Because the annular ring cannot move away from the angular flange until a sufficient amount of fluid moves through the fluid passageway 66 from the proximal reservoir 60 to the distal reservoir 62, the device will not inadvertently open due to short pressure impulses within the bladder.

Another advantage of the present embodiment is that it provides for protection against over-pressurization of the bladder. As explained above, in order to operate the device to allow urine flow, it is required to apply a sustained pressure of a predefined magnitude for a predefined duration of time to the exterior of the distal membrane 68. This sustained pressure is normally above the level which is comfortable for the individual in whom the device is positioned, and therefore it is unlikely that the bladder would become full and reach this pressure level without the individual becoming aware of it. In the event the individual is unconscious or otherwise unable to operate the device to void the bladder, a high pressure in the bladder due to the bladder being full would be sustained for a sufficiently long duration of time to cause the device to open to allow urine to flow. This fail-safe feature reduces the risk that the pressure in the bladder might rise to an unsafe level and also reduces the risk of damage to the bladder or kidneys.

*Alternative embodiment.* Figure 5 shows an alternative embodiment of the urethral device of Figure 1. In this alternative embodiment, the main portion 87A includes seminal ports 97. These seminal ports provide a relatively unobstructed pathway for seminal fluids to pass from the seminal ducts to the urethra 4. The seminal ports 97 are formed by a stamping process that precisely locates and shapes them. The size, shape, and position of the seminal ports 97 can be configured to the anatomical requirements of the individual.

## II. SECOND EMBODIMENT.

A second embodiment of an indwelling urethral device used to control urine flow in an individual is shown in Figures 6-9. The second embodiment includes some components which are similar to those in the first embodiment, and such similar components are indicated by the same numerals incremented by "200." The second embodiment differs from the first embodiment in that it uses a magnetic actuator assembly instead of a hydraulically actuated assembly to control fluid access into the internal fluid-flow passageway of the device. In the second embodiment of the urethral device, a first magnet, which is located external of the body of the individual in whom the device is positioned, is brought into proximity of the abdominal region of the individual close to the indwelling device. The magnetic field of the first magnet is used to rotate a second magnet located inside the indwelling intraurethral device. The second magnet effects operation of the valve of the indwelling intraurethral device to allow urine to flow through the device. The flow-control mechanism used in the second embodiment requires very little force for activation and thus offers the advantage that the sizes of the two cooperating magnets used to activate the device can be relatively small. In addition, as in the first embodiment, the actuating components are preferably located in a portion of the device outside the flow path of the urine being discharged through the device.

Referring to Figure 6, an expanded elevation view of the second embodiment is shown. A urethral device 210 is positioned within the bladder 201, the bladder neck 202, and urethra 204. The device 210 has a body 220 with a proximal portion 212 terminating at a proximal end 213 and with a distal portion 214 terminating at distal

end 215. The body 220 has a wall 222 with an external surface 224 and has a generally tubular shape around an axis 217. The cross-sectional shape of the body 220 may be generally round or may be flattened to conform to the anatomical shape of urethra 204.

The body 220 includes a main portion 287 and a first casing 288. The first casing 288 has drainage ports 216. Located in the first casing 288 is a bellows valve 242, an ultrasoft annular ring 238, and a plug 241 having a distal portion which forms an angular flange 240. Referring to Figures 7 and 8, the bellows valve 242 is connected at its proximal end to the annular ring 238 and is attached at its distal end to a mounting flange 280. The mounting flange 280 is connected to the first casing 288, as in the first embodiment. The bellows valve 242 is deformable in length along the axis 217. Movement of the proximal end of the bellows valve 242 displaces the annular ring 238 along the axis 217. A fluid passageway 243 extends through the annular ring 238 and communicates with a distal fluid passageway 221 that extends through the main portion 287 to the distal opening 219 at the distal end 215 of the urethral device 210. A coupling insert 292 is bonded to the tubing 284 of the main portion 287 at the distal end 215 of the urethral device 210. The coupling insert 292 can be used in cooperation with an insertion tool. In addition, at least one marker 290 can be located along the device, for example, between the mounting flange 280 and the first casing 288. All the above components may be similar or identical to those in the first embodiment.

The body 220 also includes a second casing 289. Unlike the second casing 89 of the first embodiment, the second casing 289 in the second embodiment does not include actuator ports. Instead, the second casing 289 of this second embodiment is sealed so that the components located inside the casing 289 are not exposed to the bladder environment.

Located inside the second casing 289 is a sealed proximal cavity 226. An internal magnet 291 is located in the proximal cavity 226 and mounted for limited rotation about the axis 217. To provide for this rotation, a proximal pin 262 is connected to a proximal end of the magnet 291 and is received in a proximal journal 264 located in a proximal wall of the proximal cavity 226. A distal pin 266 is

connected to a distal end of the magnet 291 and is received in a distal journal 269 located in a distal wall of the proximal cavity 226. The distal pin 266 extends through the distal wall of the proximal cavity 226 into a flange cavity 271. The distal end of the distal pin 266 is connected at its distal end to a barrel cam 268 which is located in the flange cavity 271.

A cam housing 270 is located in the flange cavity 271. A proximal end of the central shaft portion 273 of an actuator rod 272 extends into the flange cavity 271 through an opening centrally located in a distal wall of the flange cavity 271. (Unlike the actuator rod 72 in the first embodiment, the actuator rod 272 in the second embodiment does not include a proximal disk.) The central shaft portion 273 of the actuator rod 272 is slidable relative to the distal wall of the flange cavity 271. The cam housing 270 is connected at its distal end to the proximal end of the central shaft portion 273 of the actuator rod 272. The cam housing 270 is positioned relative to the barrel cam 268 so that when the magnet 291 rotates, the distal surface 277 of the barrel cam 268 slidably engages the proximal surface of the follower 275 causing the actuator rod 272, which is connected to the cam housing 270, to move axially.

The interior of the second casing 289 including the proximal cavity 226 and the flange cavity 271 is filled with a fluid 295. The distal end of the interior of the second casing 289 is sealed by an actuator rod boot 281.

*Operation:* The urethral device 210 is positioned in the urethra 204 using any of the techniques described above in connection with the first embodiment. Figure 6 shows the urethral device 210 after it has been positioned in the urethra. In Figures 7 and 8, the urethral device 210 is in the closed position. As in the first embodiment, urine is prevented from entering the urethral device 210 by the sealing of the inner surface of the annular ring 238 to the angular flange 240.

To place the urethral device 210 in the open mode, an external actuation magnet 326 is positioned close to the urethral device 210, as shown in Figure 9. In a present embodiment, the external magnet 326 is positioned within approximately five inches of urethral device 210 and approximately perpendicular to the axis 217. The internal magnet 291 of the urethral device 210 rotates because its south-poled surface

296 is magnetically attracted and drawn towards the north-poled surface 328 of the external actuation magnet 326. The speed of rotation of the internal magnet 291 is controlled by the viscosity of the fluid 295 in the sealed proximal cavity 226 and the clearance between the magnet 291 and the internal surface 227 of the second casing 289. The control of the rotation of magnet 291 provides a time delay mechanism in the device. The distal pin 266 of the internal magnet 291 is connected at its distal end to the barrel cam 268 so that rotation of the internal magnet 291 results in similar angular displacement of the barrel cam 268. The distal cam face 277 of the barrel cam 268 slidably engages the follower 275, causing the cam housing 270 to displace the actuator rod 272 along the axis 217 in a distal direction. Because the distal ring 278 of the actuator rod 272 is fixed to the annular ring 238, distal axial movement of the actuator rod 272 causes the annular ring 238 to likewise move distally. Displacement of the annular ring 238 results in the compression of the bellows spring 244 and the resultant shortening of the flexible bellows valve 242. This causes the separation of the annular ring 238 from the angular flange 240, exposing the opening 239 in the proximal end of the annular ring 238. Urine from the bladder is allowed to pass through the drainage ports 216 and the opening 239 and then enter the passageway 243 located inside the annular ring 238. Flow of urine continues through the distal fluid passageway 221 located inside the main portion 287 and out from the distal opening 219 in the distal end 215 of the device 210 with only minimal restriction.

After the bladder is substantially empty, the flow of urine subsides. After the flow of urine subsides, the device can be closed to prevent unintentional urine drainage until the individual is ready to empty his or her bladder again. The device is closed by removing the external actuation magnet 326 beyond the required activation range of five inches or less. This eliminates the force that is transmitted through the internal magnet 291, the cam 268, the cam housing 270, and the actuator rod 272 and that maintains the bellows spring 244 in compression. Without the opposing force created by the external magnet, the biasing force of the bellows spring 244 moves the actuator rod 272 and the attached annular ring 238 proximally. This causes the proximal lip 233 of the annular ring 238 to seal against the angular flange 240, preventing the entry of urine into the flow passageway 243 in the device. The proximal movement of

actuator rod 272 likewise causes the cam housing 270 to rotate the barrel cam 268 back to its initial position.

*Materials:* Except as noted below, the components of the second embodiment are the same as or similar to the corresponding components in the first embodiment.

The angular flange 240 acts as a sealing surface to the annular ring 238. The present material is a Teflon TFE and Acetal (Delrin AF) blend. The angular flange 240 has an approximate 15-degree distal taper that allows for a slight stretch of the annular ring 238 as the annular ring 238 is pushed in to the angular flange 240 by the bellows spring 244. The proximal portion of the angular flange 240 is a stepped, cylindrical surface to interface with the bellows valve 242 and the bellows spring 244. The outer diameter of the angular flange is approximately 5.3 mm (.210 inches ) and 3.8 mm (.149 inches ). The internal follower is sized and shaped to cooperate with the helix of barrel cam 268.

The fluid 295 is preferably a medical grade glycerin with an ambient viscosity of approximately 800 centi-poise at 70 degrees Fahrenheit. The fluid 295 is retained within the proximal cavity 226 and the flange cavity 271 by an actuator rod boot 281, which is easily deformed to accommodate the axial travel of the actuator rod 272. Deformation of the actuator rod boot 281 allows for the necessary conservation of volume required within a closed, fluid-filled system.

The flexible bellows valve 242 is constructed from a bellows spring 244 within a layer formed by a thin polypropylene sleeve or layer 245. In one embodiment, the bellows spring 244 is formed from 302 stainless steel wire. The spring constant of the bellows spring 244 is approximately 4.5 N/m (.026 lbf/in) using an approximately .15 mm (.006 inches) wire wound with 6 active coils and 2 dead coils. The sleeve 245 is formed using a polypropylene film approximately .013 mm (.0005 inches) thick. Alternatively, the bellows valve 242 may be constructed from Shore A 30 durometer medical grade silicone rubber (i.e. NuSil MED 4-4220). In this construction, the bellows valve 242 provides a sealed interface between the angular flange 240 and the tubing of the main portion 287. The bellows valve 242 is constructed with approximately a .010 inch wall. The inner diameter is approximately 5.5 mm

(.216 inches), and the outer diameter is approximately 6.8 mm (.266 inches) with approximately a 45-degree bellows wall angle. This construction provides approximately 2.5 mm (.100 inches) axial displacement.

The proximal pin 262 is formed from nonmagnetic, 304 stainless steel wire, approximately .020 inches in diameter.

Both the proximal journal 264 and distal journal 269 are cylindrical components made from a Teflon TFE and Acetal (Delrin AF) blend. The proximal journal 264 is press fit into the proximal wall of the second casing 289.

The distal pin 266 is formed from a nonmagnetic, 304 stainless steel wire, approximately .020 inches in diameter. Its length is sufficient to engage the barrel cam 268 in order to transmit rotation of the internal magnet 291 to the barrel cam.

The barrel cam 268 is a cylindrical component with an external helix. The external helix acts as a guide rail upon which the follower 275 slides. The barrel cam is constructed from a Teflon TFE and Acetal (Delrin AF) blend. The barrel cam is press fit onto the distal end of distal pin 266.

The internal magnet 291 is a Neodymium 45 ceramic material purchased from PERMAG, a division of Dexter Magnetic Materials, as part number PN45C0140B, magnetized through the diameter. The internal magnet 291 is cylindrical with an outside diameter of approximately .140 inches by approximately .500 inches long and may have two cylindrical recesses to receive the distal and proximal pins 262 and 266.

The external actuation magnet 326 is a Neodymium disk magnet, Part No. ND030N-27, from The Magnet Source™.

*Advantages:* The second embodiment includes many of the same advantages as the first embodiment. Like the first embodiment, the magnetically actuated embodiment has its actuation components located outside the urine fluid flow path. This provides the advantage that the dimensions of the urine fluid flow passageway can be relatively large thereby providing for a correspondingly high flow rate and relatively complete voiding of the bladder. This is advantageous for reducing discomfort and the risk of infection.

One advantage provided by the magnetically actuated embodiment is that its

operation is controlled by the external magnet. Therefore, the second embodiment would be useful for those individuals who might be unable to exert the necessary muscular activity to operate the first embodiment. With the second embodiment, the external magnet is used to positively activate the device to effect voiding of the bladder. Because of viscous shear damping effects created by the magnet 291 rotating in the fluid 295, the external magnet 326 is positioned in close proximity to the indwelling device for a preset duration of time, e.g. 3-5 seconds or more, to cause the device to open to let urine to flow through it. This avoids unintentional activation which might be caused by accidentally passing the magnet close to the device or by short, transient pressure peaks which might result from laughing, coughing, exercising, etc.

Even though the magnetically actuated embodiment requires the sustained application of the external magnetic field for activation, it also provides an over-pressure fail-safe feature. As mentioned above in connection with the first embodiment, the bladder pressure acting upon the proximally facing surface area of the proximal lip of the annular ring is transformed into a distally directed force applied to the annular ring. For this reason, the proximally facing surface area of the proximal lip of the annular ring is made relatively small in area so that the resultant distally directed force applied to the annular ring is likewise relatively small. Under normal operating conditions, this distally directed force is insufficient to overcome the proximal biasing force of the bellows spring which maintains the fluid seal between the annular ring and the angular flange. However, if the bladder pressure becomes unusually high (for example, when the individual is unconscious and unable to activate the device), the distally directed force resulting from the application of the bladder pressure upon the proximally directed surface area of the annular ring becomes sufficient to overcome the biasing force of the bellows spring and causes compression of the bellows. Once the bladder pressure is sufficient to compress the bellows spring, the device is opened and urine can be voided from the bladder. Thus, the second embodiment provides this automatic fail-safe feature to reduce the risk that the individual might be unable to activate the device to empty his or her bladder.

III. THIRD EMBODIMENT.

A third embodiment of an indwelling urethral device 410 used to control urine flow in an individual is shown in Figures 10 and 11. The components in the third embodiment are similar or identical to those in the first embodiment, except as noted below. Like the first embodiment, the embodiment shown in Figures 10 and 11 is hydraulically actuated. The embodiment in Figures 10 and 11 includes a different kind of biasing arrangement compared to the embodiment in Figures 1-5. In the embodiment in Figures 10 and 11, the force threshold which is required to be overcome to open the bellows valve is substantially non-linear. This non-linear force threshold includes a relatively high force along an initial displacement of the bellows valve and a relatively low force along the remainder of the displacement. The initial displacement is relatively small compared to the remainder of the displacement. For example, if the initial displacement is .004 inches (.1 mm), the remainder of the displacement is approximately .096 inches (2.4 mm). This non-linear force threshold, particularly when combined with damping of the actuator, provides a urethral device with favorable operating characteristics.

The third embodiment 410 includes a second casing 489 located at a proximal portion 412 of the body 420. The second casing 489 includes actuation ports 418 (shown in Figure 10) which permit fluid and/or fluid pressure to pass from outside the second casing 489 to the interior 461 thereof. A sealed proximal fluid reservoir 460 and a sealed distal fluid reservoir 462 are located inside the second casing 489. The proximal and distal fluid reservoirs 460 and 462 are filled with a fluid 458. A proximal membrane 452 is located inside the second casing and forms at least a part of the wall which defines the proximal fluid reservoir 460. The proximal membrane 452 is located in the interior 461 of the second casing 489 so that it is exposed to the fluid pressure in the bladder through the actuator ports 418. A distal membrane 468 is located inside the second casing and forms at least a part of the wall which defines the distal fluid reservoir 462.

The proximal and distal reservoirs 460 and 462 communicate with each other through an opening 466 located in a journal sleeve 464. A plunger 465 is located in the journal sleeve 464. The plunger 465 has a length such that a proximal end of the

plunger 465 is located in the proximal reservoir 460 and a distal end of the plunger 465 is located in the distal reservoir 462. The opening 466 through the journal sleeve 464 has a size relative to the plunger 465 that permits the plunger 465 to move freely proximally and distally relative to the journal sleeve 464. Further, the opening 466 through the journal sleeve 464 is sized with respect to the size of the plunger 465 in order to provide a restricted fluid path along the outside of the plunger 465 through the opening 466 between the proximal and distal reservoirs 460 and 462 by which the fluid 458 can pass between the reservoirs.

A distal end of the plunger 465 connects to a proximal end of a central shaft portion 473 of an actuator rod 472. The central shaft portion 473 of the actuator rod 472 extends from the distal end of the plunger 465 through the distal reservoir 462, through the distal membrane 468, and through a bore 447 located in a plug 441. The distal end of the central shaft portion 473 of the actuator rod 472 connects to a distal ring 478 of the actuator rod 472. The distal ring 478 connects to the inside of an ultrasoft annular ring 438 located at a proximal end of a bellows valve 442. Located at the proximal end of the annular ring 438 is a soft flexible proximal lip 433.

Located inside the second casing 489 is a latching mechanism. The latching mechanism provides for a non-linear force which is required to be overcome in order to open the urethral device to permit fluid to flow from the bladder through the device. In the embodiment of Figures 10 and 11, the latching mechanism comprises a latch spring 456. The latch spring 456 is located in the distal reservoir 462. The latch spring 456 is comprised of an arm 455 connected at one end to the journal sleeve 464. In the embodiment shown, the arm 455 is connected at its proximal end to the outer circumference of the journal sleeve 464. The other end of the arm 455 is unattached or otherwise formed to allow limited movement relative to the casing wall and/or the plunger 465. The arm 455 is formed of a resilient, shape memory material. The arm 455 may be formed with a bowed or leaf shape. The distal end of the arm 455 may be formed have a small rim. When the plunger 465 is in its most proximal position, the distal end of the arm 455 engages the distal end of the plunger 465. If the distal end of the arm 455 has a rim, the rim may extend over the distal edge of the plunger 465. When the distal end of the arm 455 engages the distal edge of the plunger 465, the

plunger 465 is permitted to have no or only limited axial movement. This axial movement, if permitted, is not of a magnitude sufficient to allow the attached ultrasoft ring 438 (which is attached to the plunger 465 by way of the actuator rod 472) to move away from the angular flange 440.

This embodiment may be operated in a manner similar to the first embodiment. Fluid pressure in the bladder is transferred to the proximal membrane 452 in the interior 461 of the second casing 489 through the actuation ports 418. Distal movement of the plunger 465 is prevented by the distal end of the latch spring 456 which bears against the distal edge of the plunger 465. Distal movement of the plunger 465 is also opposed by a biasing force from the bellows spring 444 which is transferred to the plunger 465 through the actuator rod 472. Of these, the opposing force provided by the latch spring 456 is relatively larger than the force provided by the bellows spring 444.

When fluid pressure in the bladder is sustained at a predetermined level for a predetermined duration of time, the device opens to allow urine to flow from the bladder into the drainage ports 416, through the device 410 out the body of the person in whom the device is positioned. Sustained fluid pressure against the proximal membrane 452 causes sufficient force to act on the plunger 465 to overcome the biasing force of the latch spring 456. The latch spring 456 then resiliently bends away from the distal edge of the plunger 465. When the distal end of the latch spring 456 is no longer in engagement with the distal end of the plunger 465, it rides along the exterior side of the plunger. Further distal movement of the plunger 465 is opposed by the frictional force of the latch spring 456 bearing on the outside of the plunger 465, the opposing biasing force of the bellows spring 444, and the frictional force associated with moving the fluid 458 through the opening 466 from the proximal reservoir 460 to the distal reservoir 462. The combination of these forces is less than the force resulting from application of pressure from the bladder to the proximal membrane 452. Therefore, the plunger 465 moves distally causing the annular ring 438 to move away from the angular flange 440. Because the frictional force of the latch spring 456 against the outside of the plunger is substantially less than the biasing force that the latch spring 456 applies against the distal edge of the plunger 465, a substantially non-

linear force opposing opening of the device results.

The device is closed in a manner similar to the first embodiment. When the bladder is substantially empty, the flow through the device diminishes. The individual relaxes so that relatively high bladder pressure is not sustained. This has the effect of reducing the force applied to the proximal membrane 452 below the opposing force of the bellows spring 444. This causes the plunger 465, which is connected to the bellows, to move proximally and likewise causes the fluid 458 which had been in the distal reservoir 462 to flow to the proximal reservoir 460 through the opening 466. When the plunger 465 is moved to its proximal position, the latch spring 456 engages the distal edge of the plunger 465 securing it in the proximal position. When the plunger 465 is moved to its proximal position, the ring 438 is seated on the angular flange 440 and the device is sealed to prevent flow of urine.

In this embodiment, the latching mechanism is described as being formed of a latching spring that engages a plunger to provide a relatively high biasing force along an initial distal displacement of the bellows and a relatively lower force along a remaining portion of the distal displacement of the bellows. Other kinds of mechanisms and means can be utilized to provide this kind of operating characteristic. For example, various other kinds of springs, pins, latches, cams, threads arrangements can be used to provide this kind of operating characteristic. Alternatively, this kind of operating characteristic can also be provided by magnetic means.

This embodiment has the advantage that the latching mechanism provides a well defined operating threshold to allow urine to be drained through the device. This may make the device easier to adapt for different individuals and may make the device easier to use for some individuals. A significant advantage provided by this embodiment is that is has a relatively low activation threshold which makes the device relatively easy to use. Another significant advantage of this embodiment is that despite the relatively low activation threshold, it is relatively insensitive to brief, transient pressure surges, which may occur due to exercise, coughing, etc. Still another advantage of this embodiment is that once a bladder pressure of sufficient magnitude and duration is applied, the device opens all the way relatively quickly due to the non-linear characteristics provided by the latching mechanism. This allows for a relatively

large flow passage for urine which in turn provides for relatively quick and thorough voiding. Still further, once the device is open, it stays fully open due to the damping characteristics of the actuator thereby providing for relatively complete voiding of the bladder.

In another alternative embodiment, the plunger shown in this embodiment may be incorporated into a urethral device that does not have a latching mechanism, such as the first embodiment disclosed above. In such an alternative embodiment, the device would include a plunger that pushes an actuator rod to open the bellows valve, but would not include a latch spring. Such an embodiment may optionally use a proximal spring to assist in restoring the device to a closed position or alternatively the proximal spring may be omitted and the biasing force of the bellows spring would be used to close the device.

## IV. FOURTH EMBODIMENT.

A fourth embodiment of an indwelling urethral device 610 used to control urine flow in an individual is shown in Figure 12. The components in the fourth embodiment are similar or identical to those in the second embodiment, except as noted below. Like the second embodiment, this embodiment includes a magnetic actuator and like the third embodiment, the embodiment of Figure 12 includes a latching mechanism that provides for a non-linear force which is required to be overcome to open the device to allow urine to be drained from the bladder.

The fourth embodiment 610 includes a second casing 689 located at a proximal portion 612 of the body 620. Like the third embodiment, described above, the second casing 689 includes actuation ports 618 which are located along the second casing 689 (similar to those shown in Figure 10). Located inside the second casing 689 is a sealed cavity 626 having a proximal portion 660 and a distal portion 662. The sealed cavity 626 is filled with a fluid 658. A flexible proximal membrane 652 forms part of the wall of the proximal portion 660 of the sealed cavity 626 and a flexible distal membrane 668 forms part of the wall of the distal portion 662 of the sealed cavity 626. The proximal and distal portions 660 and 662 of the sealed cavity 626 are connected by a fluid passageway 666 which is formed by a journal sleeve 664 fixed in the proximal cavity

626 of the second casing 689.

An internal magnet 691 is located in the proximal cavity 626 and mounted for limited rotation about the axis 617. To provide for this rotation, the magnet 691 is received in the passageway 666 of the cylindrical journal sleeve 664. A proximal end of the magnet 691 is formed into a cam surface 677. This cam surface 677 bears against a cam follower 675 formed as part of the proximal end of the journal sleeve 664. The cam surface 677 of the magnet 691 is positioned relative to the cam follower 675 of the journal sleeve 664 so that when the magnet 691 rotates, the cam surface 677 at the proximal end of the magnet 691 slidably engages the surface of the follower 675 causing the magnet 691 to move axially.

A central shaft portion 673 of an actuator rod 672 is connected to the distal end of the magnet 691. The central shaft portion 673 of the actuator rod 672 extends from distal end of the magnet 691 through the distal portion 662 of the cavity 626, through the distal membrane 668, and through a bore 647 located in a plug 641. The distal end of the central shaft portion 673 of the actuator rod 672 connects to a distal ring 678 of the actuator rod 672. The distal ring 678 connects to the inside of an ultrasoft annular ring 638 located at the proximal end of a bellows valve 642.

Located inside the second casing 689 is a latching mechanism. In the embodiment of Figure 12, the latching mechanism comprises a latch spring 656 located in the distal portion 662 of the sealed fluid cavity 626. The latch spring 656 may be similar to the latch spring in the previously described embodiment. The latch spring 656 is comprised of an arm 655 connected at its proximal end to the inside wall of the second casing 689. When the magnet 691 is in its most proximal position, the distal end of the arm 655 engages the distal end of the magnet 691. When the magnet 691 is in its proximal position, the ultrasoft ring 638 which is attached to the magnet 691 via the actuator arm 672, is seated on the angular flange 640.

This embodiment may be operated in a manner similar to the second (magnetically actuated) embodiment, described above. To place the urethral device 610 in the open mode, an external actuation magnet, similar to the device 326 shown in Figure 9, is positioned within approximately five inches of urethral device 610 and approximately perpendicular to the axis 617. The external magnet attracts the internal

magnet 691 tending to cause the internal magnet to rotate its north-south face toward to the external magnet. However, since the end of the magnet 691 includes the cam surface 677, rotation of the magnet 691 is accompanied by axial movement in a distal direction which is opposed by the force of the latch spring 656. Once the latching force of the latch spring 656 is overcome, continued rotation is opposed by the substantially lower frictional force of the latch spring 656 riding on the outside surface of the magnet 691. In addition, the rotation of the internal magnet 691 is damped by the viscosity of the fluid 658 in the sealed proximal cavity 626 and the friction associated with moving the fluid 658 from the proximal portion 660 to the distal portion 662 of the cavity 626.

As the magnet is rotated, the proximal cam surface 677 of the magnet 691 slidably engages the follower 675, causing the magnet 691 and actuator rod 672 to move along the axis 617 in a distal direction. Because the distal ring 678 of the actuator rod 672 is fixed to the annular ring 638, distal axial movement of the actuator rod 672 causes the annular ring 638 to move distally separating the annular ring 638 from the angular flange 640. Urine from the bladder is allowed to pass through the drainage ports 616 and out from the distal opening in the distal end of the device.

After the bladder has been emptied, closing of the device may be accomplished by removing the external magnet thereby allowing the biasing force of the bellows spring 644 to move the annular ring 638 proximally to seal against the angular flange 640. When the magnet 691 is moved to its proximal position, the latch spring 656 engages the distal edge of the magnet 691 securing it in the proximal position.

This embodiment includes a fail-safe feature that allows for drainage of urine from the bladder to avoid injury to the kidneys if the patient does not operate the device with the magnet. If the patient does not operate the device when the bladder becomes full, the pressure in the bladder rises. This bladder pressure is applied to the proximal membrane 652 through the actuation ports 618 located in the second casing 689. When the bladder pressure reaches a predetermined magnitude for a sustained period of time, sufficient fluid 658 is caused to flow from the proximal portion 660 of the sealed cavity 626 to the distal portion 662 via the fluid passageway 666 formed in the journal sleeve 664 past the magnet 691. This is sufficient to cause movement of

the annular ring 638 distally to open the device to allow urine to flow through the device to relieve the high pressure condition in the bladder. The annular ring 638 may open fully when activated in this manner by the high pressure condition applied to the proximal membrane or alternatively, the annular ring 638 may open only slightly to allow for a slow, weeping or seeping flow. A slow weeping or seeping flow may be preferred since it is only necessary to drain enough urine to reduce the high pressure condition and therefore it is not necessary to open the device completely which would result in complete voiding of the bladder. The latch spring 655 may be used to provide for this weeping flow operating characteristic. The latch spring 655 may continue to engage the distal edge of the magnet 691 yet provide for slight movement of the actuator rod 672 to allow the bellows valve 642 to open.

Like the third embodiment, this embodiment has the advantage that the latching mechanism provides a well defined operating threshold to allow urine to be drained from the device. This may make the device easier to adapt for different individuals and may make the device easier to use for some individuals. Like the second embodiment, the magnetic actuator provides for positive actuation which may be desired by some individuals who do not have sufficient muscle control to use the hydraulically actuated embodiments. A significant advantage provided by this embodiment is that is has a relatively low activation threshold which permits the internal and external magnets to be relatively small and convenient to use. Another significant advantage of this embodiment is that despite the relatively low activation threshold, it is relatively insensitive to brief, transient pressure surges, which may occur due to exercise, coughing, etc. Still another advantage of this embodiment is that once a magnetic field of sufficient strength and duration is applied, the device opens all the way relatively quickly due to the non-linear characteristics provided by the latching mechanism. Still further, once the device is open, it stays fully open due to the damping characteristics associated with the magnetic actuator thereby providing for complete voiding of the bladder.

Another important advantage provided by this embodiment is the fail-safe feature. As described above, if the patient is unable to use the magnet to open the

device, high pressure conditions will cause the device to open, either fully or slightly, to allow urine flow to relieve the high pressure condition. This feature is provided automatically without the use of the magnet.

It is to be understood, however, the even though numerous characteristics and advantages of the present invention have been set forth in the foregoing description, together with details of the structure and function of present invention, the sequence or order of the specific steps, or the actual compositions, environmental conditions, and the like experienced or sensed may vary somewhat. Furthermore, it will be appreciated that this disclosure is illustrative only and that changes may be made in detail, especially in matters of shape, size, arrangement of parts, or sequence of elements of the various aspects of the invention within the principles of the invention to the full extent indicated by the broad general meaning of the terms in which the appended claims are expressed.

WE CLAIM:

1. An apparatus for placement in a urethra of an individual for control of urine flow comprising:

a tubular body sized for placement in the urethra, said tubular body having a proximal portion adapted for placement in the bladder of the individual, a distal portion opposite from said proximal portion, said tubular body having a lumen extending from a distal opening in said distal portion to a proximal opening in said proximal portion; and

a flexible bellows valve extendible between a bellows first position in which said flexible bellows valve closes said proximal opening and a bellows second position in which said flexible bellows valve exposes said proximal opening thereby permitting urine to flow from the bladder through the lumen.

2. The invention of Claim 1 further comprising:

a magnet located internally of said tubular body and movable between a magnet first position and a magnet second position in response to an applied external magnetic field, said magnet coupled to said flexible bellows and operable to move said flexible bellows between at least one of said bellows positions.

3. The invention of Claim 2 wherein said magnet is damped so that sustained application of said external magnet field is required to move said magnet between said first magnet position and said second magnet position.

4. The invention of Claim 1 further comprising:

an actuator located at said proximal portion and movable between an actuator first position and an actuator second position in response to fluid pressure inside the bladder said actuator coupled to said flexible bellows and operable to move said flexible bellows between at least one of said bellows positions.

5. The invention of Claim 4 wherein said actuator is damped so that transient pressure peaks of short duration in the bladder are ineffective to move said actuator between said actuator first position and said actuator second position.

6. The invention of Claim 1 further comprising:

a latching mechanism coupled to said bellows valve and operative to apply a force opposing movement of said bellows valve from said second position to said first position.

7. The invention of Claim 6 wherein said latching mechanism is operative to apply a relatively higher force opposing movement of said bellows valve from said second position to said first position when said bellows valve is at said second position and a relatively lower force when said bellows valve is displaced from said second position toward said first position.

8. The invention of Claim 6 wherein said latching mechanism comprises a latch spring coupled to said bellows valve.

9. An apparatus for placement in a urethra of an individual for voluntary control of urine flow comprising:

a tubular body sized for placement in the urethra, said tubular body having a proximal portion adapted for placement in the bladder of the individual, a distal portion opposite from said proximal portion, said tubular body having a lumen extending from a distal opening in said distal portion to a proximal opening in said proximal portion; and

an actuator coupled to a valve operable to open and close said proximal opening, said actuator located in said proximal portion proximal of said proximal opening.

10. The invention of Claim 9 wherein said valve further comprises:

a flexible bellows extendible between a bellows first position in which said

flexible bellows closes said proximal opening and a bellows second position in which said flexible bellows exposes said proximal opening thereby permitting urine to flow from the bladder through the lumen.

11. The invention of Claim 9 wherein said actuator is damped so that transient pressure peaks of short duration in the bladder are ineffective to cause said actuator to open and close said valve.

12. The invention of Claim 9 wherein said actuator comprises:

a magnet located internally of said tubular body and movable between a magnet first position and a magnet second position in response to an applied external magnetic field.

13. The invention of Claim 9 wherein said actuator comprises:

a fluid pressure sensor responsive to fluid pressure in the bladder.

14. The invention of Claim 9 further comprising:

a latching mechanism coupled to said actuator and operative to apply a relatively higher force opposing opening of said valve when said valve is in a closed position and a relatively lower force opposing opening of said valve when said valve is displaced from said closed second position.

15. An apparatus for placement in a urethra of an individual for control of urine flow comprising:

a tubular body sized for placement in the urethra, said tubular body having a proximal portion adapted for placement in the bladder of the individual, a distal portion opposite from said proximal portion, said tubular body having a lumen extending from a distal opening in said distal portion to a proximal opening in said proximal portion; and

a valve operable to open and close said proximal opening; and

a damped actuator responsive to an actuation force applied thereupon, said damped actuator coupled to said valve and operable to open said valve in response to application of an actuation force for a predetermined duration and to maintain said valve closed upon application of an actuation force for less than said predetermined duration.

16. The invention of Claim 15 wherein said damped actuator further comprises:

a magnet located internally of said tubular body and movable between a magnet first position and a magnet second position in response to an applied external magnetic field, said magnet coupled to said valve and operable to move said valve between at least one of two valve positions.

17. The invention of Claim 16 wherein said magnet is located in a chamber filled with a damping fluid.

18. The invention of Claim 15 wherein said damped actuator further comprises:

a fluid sensor responsive to fluid pressure inside the bladder.

19. The invention of Claim 18 wherein said fluid sensor comprises:

a first movable surface exposed to said fluid pressure inside the bladder;

a second movable surface coupled to said valve;

at least one reservoir adjacent to at least one of said movable surfaces; and

damping fluid contained in said reservoir.

20. The invention of Claim 18 wherein said fluid sensor comprises:

a first reservoir having a first surface exposed to said fluid pressure inside the bladder;

a second reservoir having a second surface coupled to said valve;

a restrictive fluid passageway connecting said first reservoir and said second reservoir; and

a damping fluid contained in said first and said second reservoirs and movable therebetween through said restrictive fluid passageway.

21. The invention of Claim 15 wherein said valve further comprises:

a flexible bellows extendible between a bellows first position in which said flexible bellows closes said proximal opening and a bellows second position in which said flexible bellows exposes said proximal opening thereby permitting urine to flow from the bladder through the lumen.

22. The invention of Claim 15 further comprising:

a latching mechanism coupled to said damped actuator and operative to apply a relatively higher force opposing opening of said valve when said valve is in a closed position and a relatively lower force opposing opening of said valve when said valve is displaced from said closed second position.

23. The invention of Claim 15 wherein said damped actuator requires a sustained actuation force to be applied thereto for said predetermined duration to open said valve.

24. An apparatus for placement in a urethra of an individual for control of urine flow comprising:

a tubular body sized for placement in the urethra, said tubular body having a proximal portion adapted for placement in the bladder of the individual, a distal portion opposite from said proximal portion, said tubular body having a lumen extending from a distal opening in said distal portion to a proximal opening in said proximal portion; and

a valve operable to open and close said proximal opening; and

a damped actuator responsive to an actuation force applied thereupon, said damped actuator coupled to said valve and operable to maintain said valve in an open

position in response to application of an actuation force and to maintain said valve in said open position for a predetermined duration after cessation of said application of said actuation force.

25. The invention of Claim 24 wherein said damped actuator further comprises:

a magnet located internally of said tubular body and movable between a magnet first position and a magnet second position in response to an applied external magnetic field, said magnet coupled to said valve and operable to move said valve between at least one of two valve positions.

26. The invention of Claim 25 wherein said magnet is located in a chamber filled with a damping fluid.

27. The invention of Claim 24 wherein said damped actuator further comprises:

a fluid sensor responsive to fluid pressure inside the bladder.

28. The invention of Claim 27 wherein said fluid sensor comprises:

a first movable surface exposed to said fluid pressure inside the bladder;

a second movable surface coupled to said valve;

at least one reservoir adjacent to at least one of said movable surfaces; and

damping fluid contained in said reservoir.

29. The invention of Claim 27 wherein said fluid sensor comprises:

a first reservoir having a first surface exposed to said fluid pressure inside the bladder;

a second reservoir having a second surface coupled to said valve;

a restrictive fluid passageway connecting said first reservoir and said second reservoir; and

a damping fluid contained in said first and said second reservoirs and movable therebetween through said restrictive fluid passageway.

30. The invention of Claim 24 wherein said valve further comprises:

a flexible bellows extendible between a bellows first position in which said flexible bellows closes said proximal opening and a bellows second position in which said flexible bellows exposes said proximal opening thereby permitting urine to flow from the bladder through the lumen.

31. The invention of Claim 24 further comprising:

a latching mechanism coupled to said damped actuator and operative to apply a relatively higher force opposing opening of said valve when said valve is in a closed position and a relatively lower force opposing opening of said valve when said valve is displaced from said closed second position.

32. An apparatus for placement in a urethra of an individual for voluntary control of urine flow comprising:

a tubular body sized for placement in the urethra, said tubular body having a proximal portion adapted for placement in the bladder of the individual, a distal portion opposite from said proximal portion, said tubular body having a lumen extending from a distal opening in said distal portion to a proximal opening in said proximal portion, wherein said proximal opening exposed to bladder when positioned in the urethra; and

a bellows coupled to said tubular body and having an end that is extendible between a first position and a second position, said bellows end operable to close said proximal opening in said first position and to expose said opening in said second position; and

an actuator located at said proximal portion, said actuator including an actuation surface coupled to said bellows end and responsive to an actuation force applied thereto and a reservoir adjacent to said surface and containing a fluid that damps transfer of movement between said actuation surface and said bellows.

33. The invention of Claim 32 wherein said actuation surface comprises an internal magnet.

34. The invention of Claim 32 wherein said actuation surface comprises at least one membrane responsive to ambient pressure in the bladder.

35. The invention of Claim 32 wherein said proximal portion of said body comprises:

a distal casing containing said bellows, said distal casing having at least one drainage port located therein to permit fluid access to said proximal opening from the bladder.

36. The invention of Claim 35 wherein said proximal portion of said body further comprises:

a proximal casing containing said actuator, said proximal casing located proximal of said distal casing.

37. The invention of Claim 36 wherein said proximal casing includes at least one actuation port providing for transfer of fluid pressure from the bladder to said actuation surface.

38. The invention of Claim 36 wherein said proximal casing comprises a sealed chamber in which is located said actuation surface and wherein said actuation surface comprises a magnet.

39. The invention of Claim 32 further comprising:

a latching mechanism operatively coupled to apply a relatively higher force opposing movement of said bellows end from said first position and a relatively lower force opposing movement of said bellows end when said bellows end is displaced from said closed first position.

40. A method of controlling urine flow from a bladder of an individual comprising:

positioning a urethral device in the urethra so that a proximal portion of the urethral device is located in fluid communication with the bladder;

maintaining a valve in a closed position to close a proximal opening into a lumen that extends through the tubular device;

continuing to maintain said valve in said closed position upon application of a force of at least a predetermined magnitude to an actuator located in said proximal portion for less than a predetermined duration of time;

opening said valve upon application of a sustained force of at least said predetermined magnitude to said actuator for at least said predetermined period of time;

continuing to maintain said valve in an open position for a second predetermined period of time until after cessation of said application of said sustained force to said actuator; and

closing said valve after said second predetermined period of time.

41. The method of Claim 40 wherein the force is applied by a magnetic field.

42. The method of Claim 40 wherein the force is applied by fluid pressure in the bladder.

43. A method of controlling urine flow from a bladder of an individual with a urethral device having a normal mode of operation and a fail-safe mode of operation, comprising the steps of:

positioning the urethral device in the urethra of the individual so that a proximal portion of the urethral device is located in fluid communication with the bladder;

maintaining a valve in a closed position to close a proximal opening into a lumen that extends through the urethral device;

in a normal mode of operation, continuing to maintain said valve in said closed position upon application of a magnetic force of at least a predetermined magnitude to an actuator located in said proximal portion for less than a predetermined duration of time; and

opening said valve upon application of a sustained magnetic force of at least said predetermined magnitude to said actuator for at least said predetermined period of time; and

in a fail-safe mode of operation, opening said valve upon application of a force resulting from a sustained fluid pressure in the bladder force for a second predetermined duration of time.

44. An apparatus for placement in a urethra of an individual for voluntary control of urine flow comprising:

a tubular body sized for placement in the urethra, said tubular body having a proximal portion adapted for placement in the bladder of the individual, a distal portion opposite from said proximal portion, said tubular body having a lumen extending from a distal opening in said distal portion to a proximal opening in said proximal portion;

a valve operable to open and close said proximal opening; and

a latching mechanism coupled to said valve and operative to apply a relatively higher force opposing opening of said valve when said valve is in a closed position and a relatively lower force opposing opening of said valve when said valve is displaced from said closed second position.

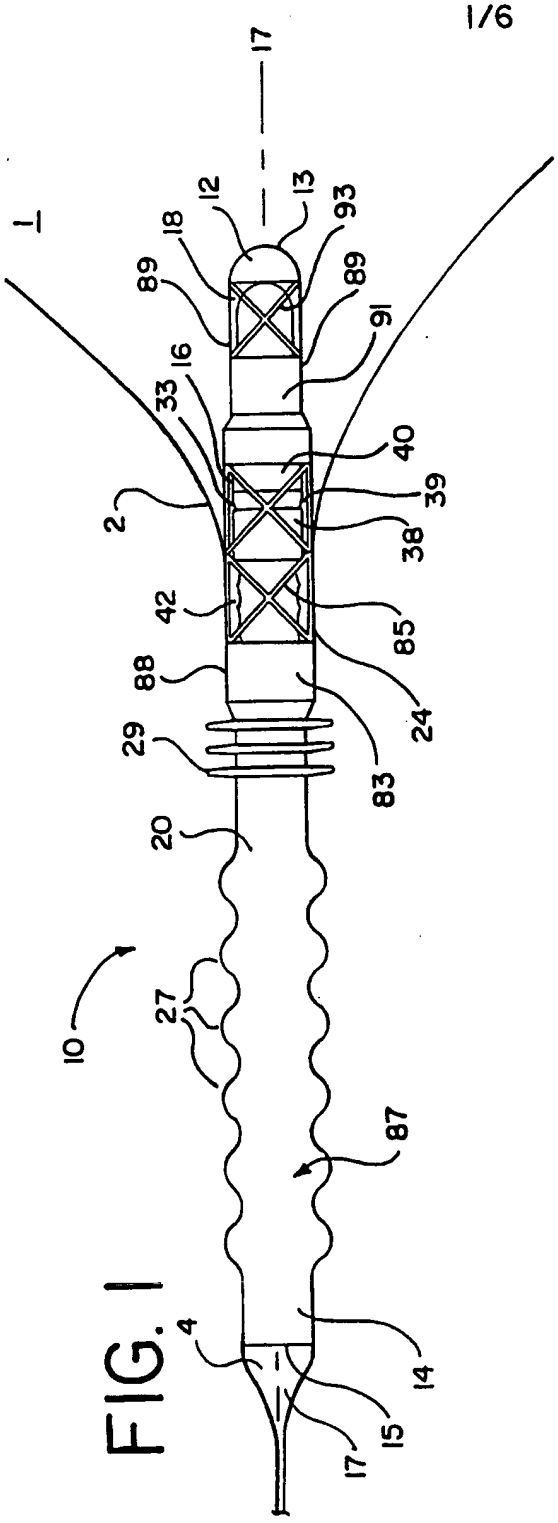
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FIG. 1

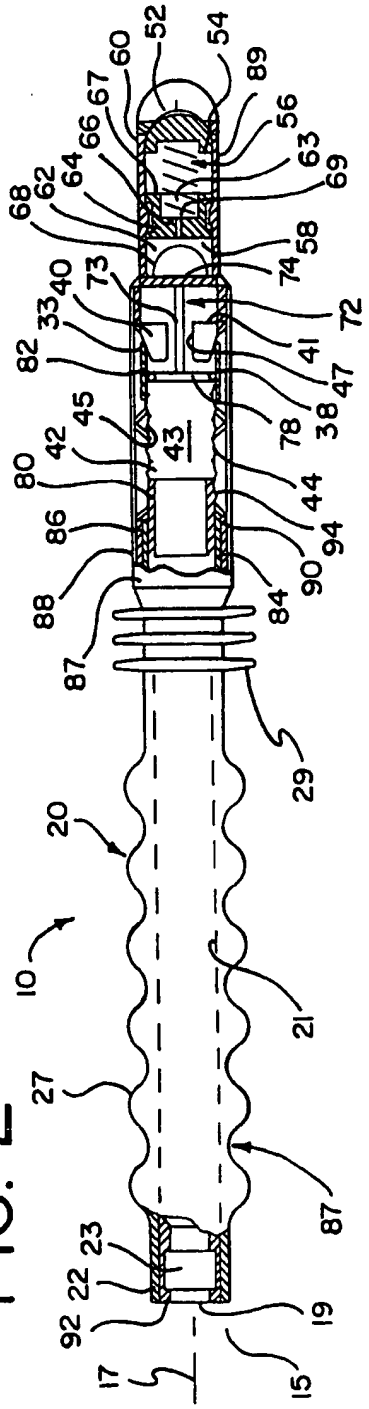
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FIG. 2

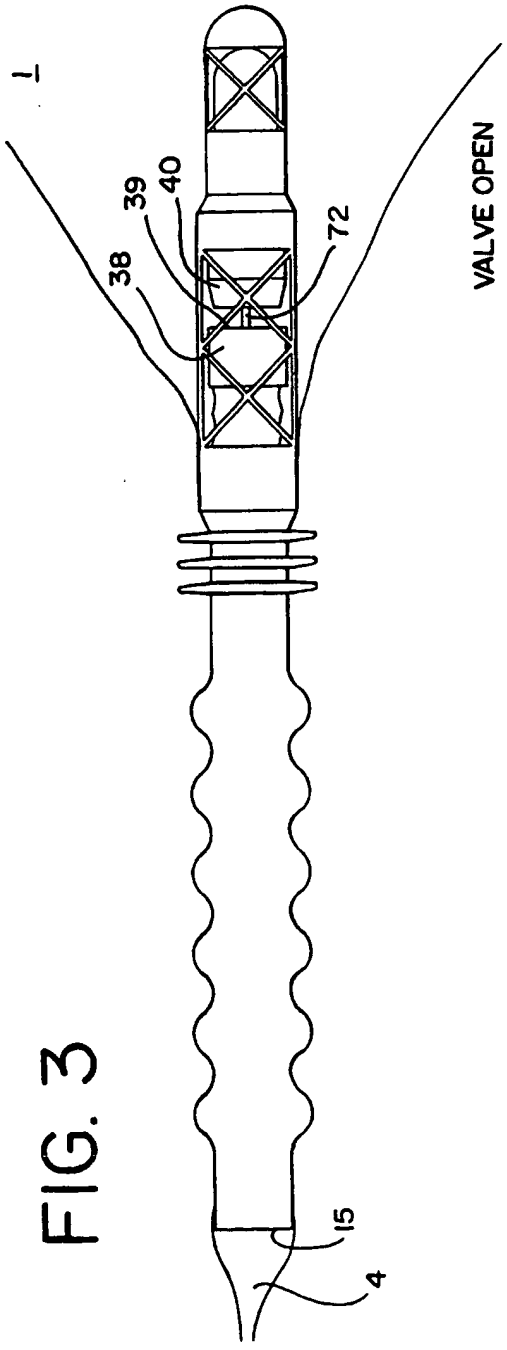


FIG. 3

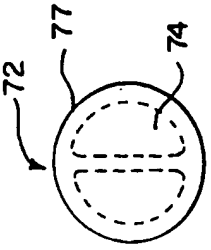


FIG. 4c

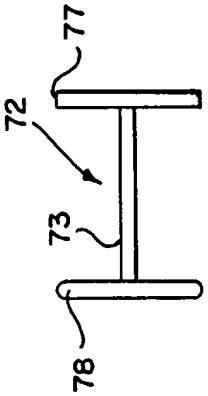


FIG. 4b

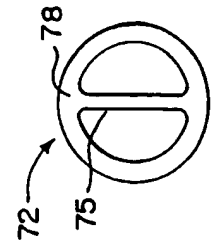


FIG. 4a

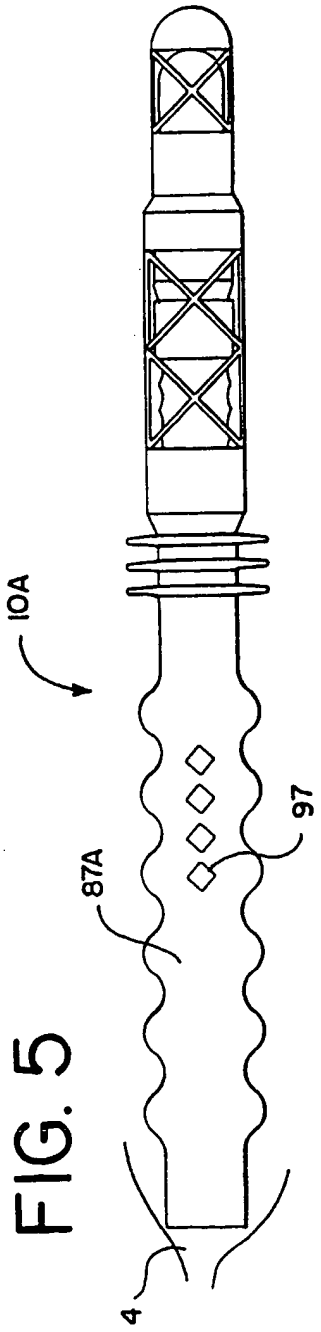
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FIG. 5

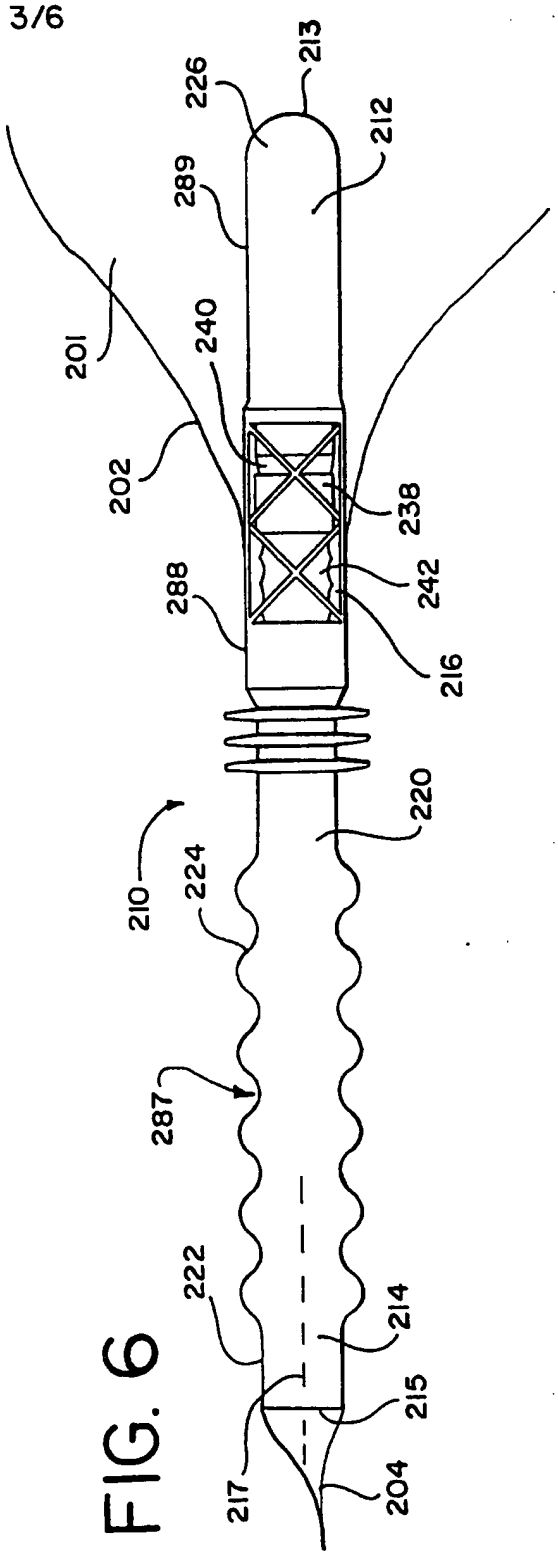
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FIG. 6

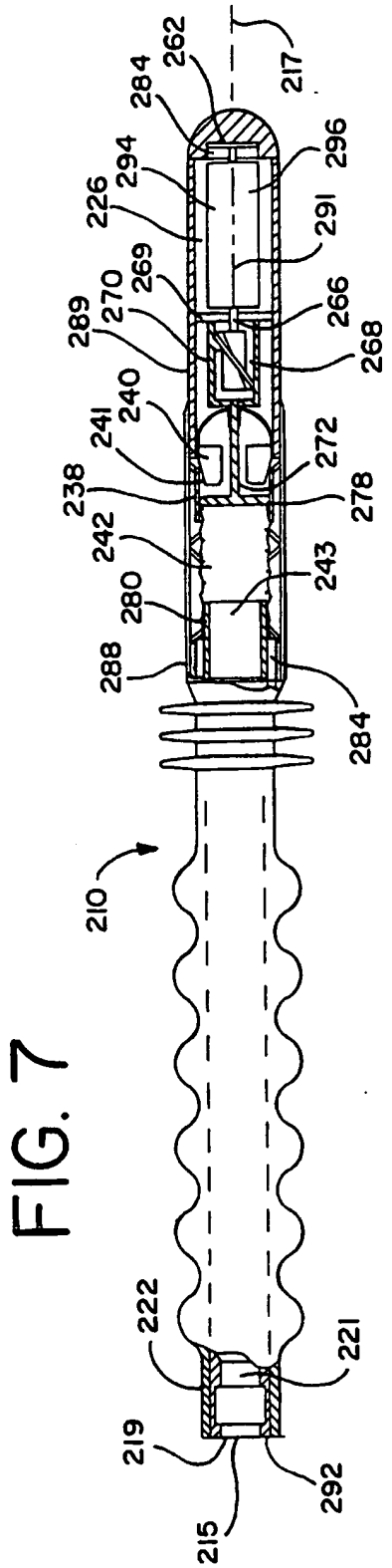
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FIG. 7

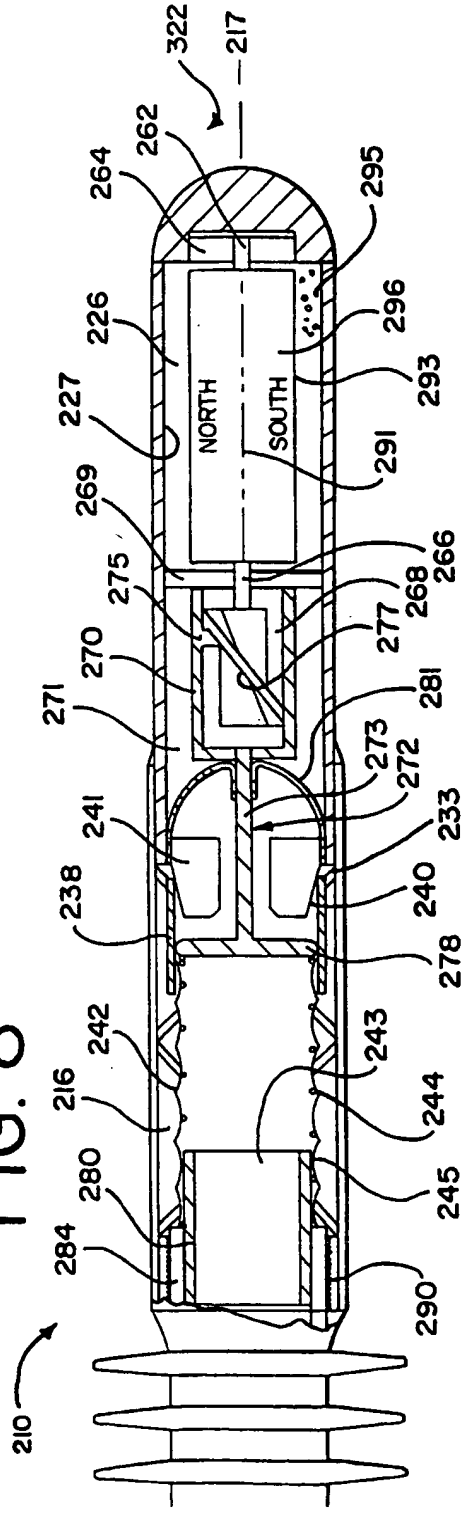
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FIG. 8

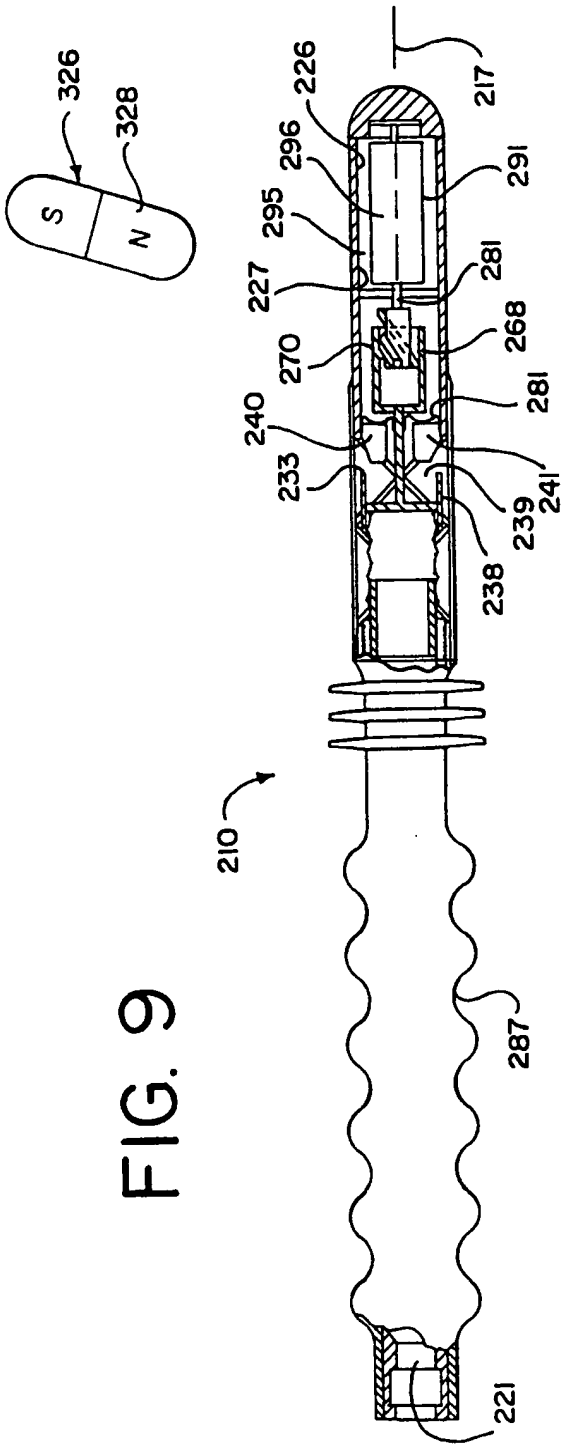
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FIG. 9

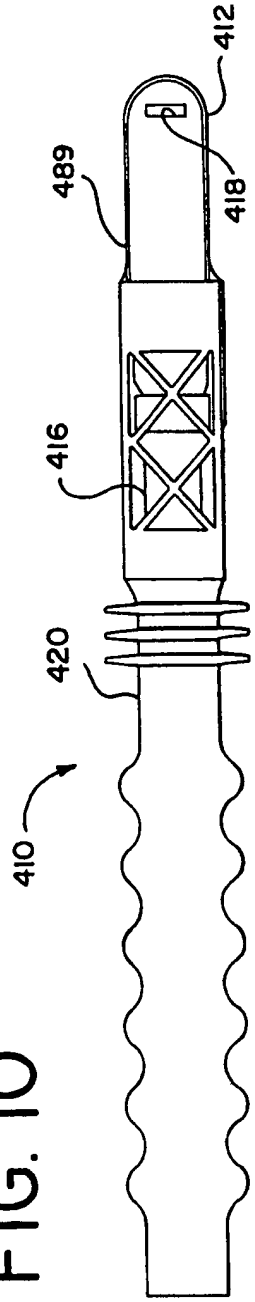
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FIG. 10

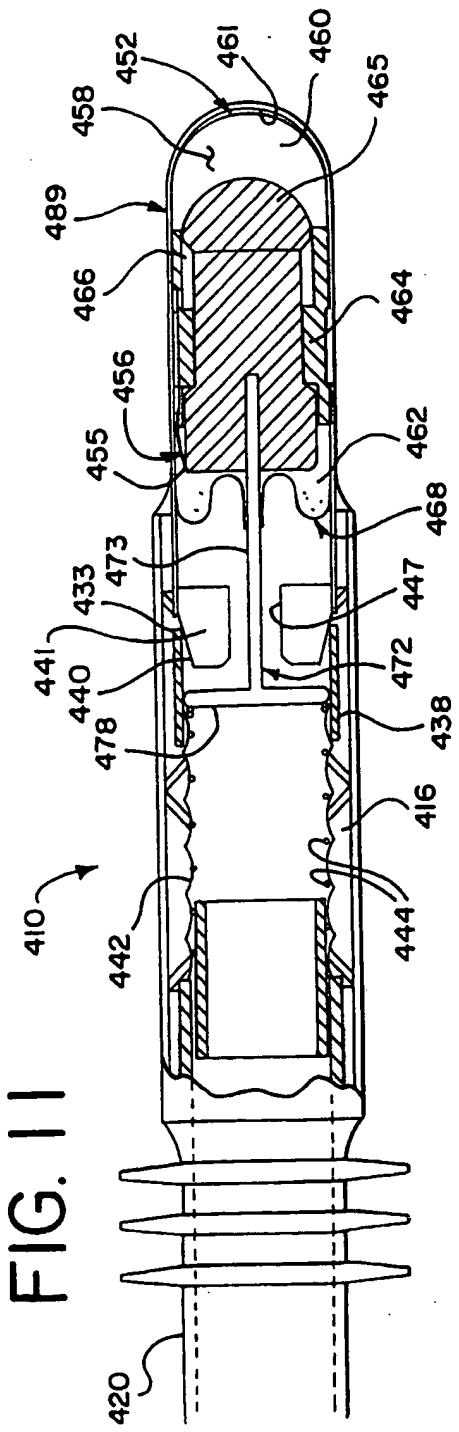
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FIG. 11

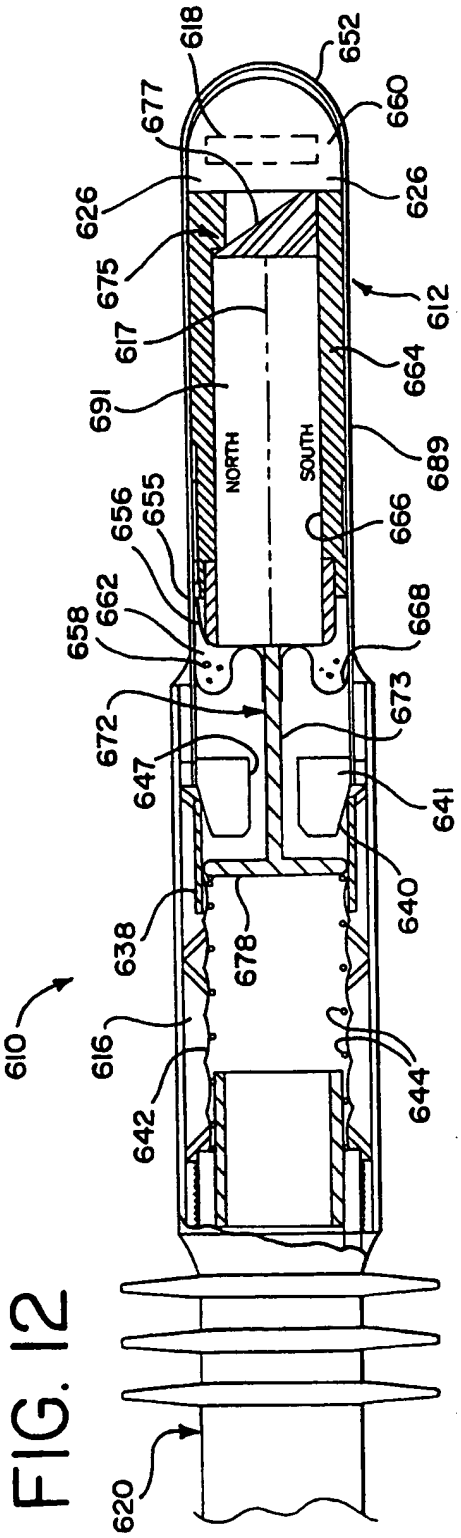
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FIG. 12

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/26509

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/00
US CL :600/29

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/DIG. 25; 600/29-31; 604/93, 96, 102

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | US 4,553,533 A (LEIGHTON) 19 November 1985, entire document. | 1-44 |
| Y | US 3,812,841 A (ISAACSON) 28 May 1974, entire document. | 1-44 |
| Y | US 5,476,434 A (KALB et al) 19 December 1995, col. 5 lines 13-44. | 13, 18, 27 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

| | | | |
|---|---|---|---|
| * | Special categories of cited documents: | "T" | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "A" | document defining the general state of the art which is not considered to be of particular relevance | "X" | document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| "E" | earlier document published on or after the international filing date | "Y" | document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "L" | document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "&" | document member of the same patent family |
| "O" | document referring to an oral disclosure, use, exhibition or other means | | |
| "P" | document published prior to the international filing date but later than the priority date claimed | | |

| | |
|---|---|
| Date of the actual completion of the international search<br>04 MARCH 1999 | Date of mailing of the international search report<br>30 MAR 1999 |
| Name and mailing address of the ISA/US<br>Commissioner of Patents and Trademarks<br>Box PCT<br>Washington, D.C. 20231<br>Facsimile No. (703) 305-3230 | Authorized officer<br>ROSALIND KEARNEY<br>Telephone No. (703) 308-3061 |

Form PCT/ISA/210 (second sheet)(July 1992)★